

APPENDIX A. Search Strategy

The following electronic databases were searched for citations.

- MEDLINE® (inception [1948] through August 6, 2010)
- EMBASE® (inception [1974] through August 6, 2010)
- Cochrane Controlled Trials Register (no date restriction)

The MEDLINE® search resulted in 693 unique citations using the disease filter and 431 citations without the disease filter. The EMBASE® search resulted in 400 citations using the disease filter and 193 without the disease filter. The Cochrane search resulted in 11 new citations. The final database had 1611 unique records.

MEDLINE search 8/6/10

1. procalcitonin = 1556
2. "Systemic Inflammatory Response Syndrome"[MeSH] OR "Pulmonary Disease, Chronic Obstructive"[MeSH] OR "Surgical Wound Infection"[MeSH] OR "Critical Illness"[MeSH] OR "Intensive Care"[MeSH] = 137013
3. ("Neutropenia"[MeSH] OR neutropenia) AND febrile = 6570
4. sepsis OR septic OR "systematic inflammatory response syndrome" OR ICU OR "critically ill" OR "intensive care unit" OR "postoperative infection*" = 184566
5. "Postoperative Complications"[MeSH] OR "Intensive Care Units"[MeSH] Limits: Humans, English = 259045
6. (2 OR 3 OR 4 OR 5) AND Limits: Humans, English= 377664
7. 1 AND 6 Limits: Humans, English = 693
8. A second result set was created in the database with set number 1 NOT set 7 = 431

EMBASE search 8/6/10

1. procalcitonin AND Limit: Humans NOT MEDLINE= 593
2. 'sepsis'/exp OR septic OR 'systemic inflammatory response syndrome'/exp OR 'copd'/exp OR 'chronic obstructive pulmonary disease'/exp OR 'febrile neutropenia'/exp OR 'postoperative infection'/exp OR 'postoperative infections'/exp OR 'postoperative complications'/exp OR 'post-surgical infection' OR 'post-surgical infections' OR 'critically ill'/exp OR icu OR 'intensive care'/exp OR 'intensive care units'/exp AND Limit: Humans= 714,937
3. 1 AND 2 = 400
4. 1 NOT 3= 193

Search Strategy For Gray Literature

Regulatory Information

FDA

Source: <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm>

Date searched: 6/3/2011

Search strategy: key word “procalcitonin assay”

Records: 3

Clinical trial registries

NIH database

Source: <http://clinicaltrials.gov/>

Date searched: 7/06/2011

Search strategy: Procalcitonin [ALL-FIELDS] AND "Completed" [OVERALL-STATUS]

Records: 29

BioMed central

Source: <http://www.controlled-trials.com/mrct/>

Date searched: 6/16/2011

Search strategy: “Procalcitonin” for completed trials

Records: 7

PhRMA

Source: <http://www.clinicalstudyresults.org/home/>

Date searched: 6/16/2011

Search strategy: Search String = “Procalcitonin”

Records: 0

WHO International Clinical Trials Registry Platform Search Portal

Source: <http://apps.who.int/trialsearch/>

Date searched: 6/16/2011

Search strategy: Search String = “Procalcitonin” for ALL recruitment status trials

Records: 55

Conference papers and abstracts

Cambridge scientific abstracts

Source: <http://www.csa.com/factsheets/cpi-set-c.php>

Date searched: 6/28/2011

Search strategy: search string “procalcitonin”

Records: 41

Scopus

Source: <http://www.scopus.com/home.url>

Date searched: 6/29/2011

Search strategy:

- 1 TITLE-ABS-KEY(sepsis) RESULT 93,988
- 2 TITLE-ABS-KEY(biomarker* OR procalcitonin) RESULT 73,083
- 3 TITLE-ABS-KEY(screen* OR test*) RESULT 3,391,802
- 4 (TITLE-ABS-KEY(sepsis) AND (TITLE-ABS-KEY(biomarker* OR procalcitonin)) AND (TITLE-ABS-KEY(screen* OR test*) RESULT 538

LIMIT: SUBJAREA(mult OR agri OR bioc OR immu OR neur OR phar OR mult OR medi OR nurs OR vete OR dent OR heal)

Records:376

Specific conferences and association meetings

Source:

Annual meeting of Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC)

Annual meeting of Infectious Diseases Society of America (IDSA)

Annual meeting of American College of Chest Physicians (ACCP)

Annual meeting of Pediatric Academic Societies (PAS)

Date searched: 6/21/2011

Search strategy: KW: "procalcitonin" or "sepsis" in the title

Records:33

Government documents

RePORTER

Source: <http://projectreporter.nih.gov/reporter.cfm>

Date searched: 6/16/2011

Search strategy: key word "procalcitonin" AND "sepsis"

Records:2

HSRPROJ

Source: http://wwwcf.nlm.nih.gov/hsr_project/home_proj.cfm

Date searched: 6/16/2011

Search strategy: key word "procalcitonin" AND "sepsis"

Records:0

AHRQ GOLD

Source: <http://gold.ahrq.gov/projectsearch/>

Date searched: 6/16/2011

Search strategy: key word "procalcitonin" AND "sepsis"

Records:1

Manufacturer database

Source: Thermo Fisher Scientific

Date posted: 6/13/2011

Date searched: 6/15/2011

Search strategy: Not applicable

Records:67

Gray Literature searching

Scopus (performed June 2011) = 376 records

Conference Papers Index (performed June 2011) = 42 records

Clinicaltrials.gov = 2 records

Meeting abstracts from 2006-2010 for:

Interscience Conference on Antimicrobial Agents and Chemotherapy (ICAAC)

Infectious Disease Society of America (IDSA)

American College of Chest Physicians

Pediatric Academic Societies (PAS)

APPENDIX B. Excluded Studies

EXC exclude

NRD not relevant disease (not relevant population)

NDE not relevant design

NRO not relevant outcome

SMN small n

Aalto, H., A. Takala, H. Kautainen, and H. Repo. Laboratory markers of systemic inflammation as predictors of bloodstream infection in acutely ill patients admitted to hospital in medical emergency. *Eur J Clin Microbiol Infect Dis* 2004 23(9):699-704.

Rec#: 4180

Exclusion Codes: SMN, EXC

Adamik, B., J. Kubler-Kielb, B. Golebiowska, A. Gamian, and A. Kubler. Effect of sepsis and cardiac surgery with cardiopulmonary bypass on plasma level of nitric oxide metabolites, neopterin, and procalcitonin: correlation with mortality and postoperative complications. *Intensive Care Med* 2000 26(9):1259-67.

Rec#: 5940

Exclusion Codes: NDE, EXC

Ahmadinejad, Z., B. Dadsetan, M. Jalili, A. Soudbakhsh, and M. Rasolinejad. Evaluation of serum procalcitonin in patients with systemic inflammatory response syndrome with and without infection. *Acta Med. Iran.* 2009 47(5):383-388.

Rec#: 11910

Exclusion Codes: NDE, EXC

Ahmadinejad, Z., A.R. Soudbakhsh, and A. Tayebi. Serum procalcitonin level in infectious and non- infectious systemic inflammatory response syndrome: A three- year study. *Tehran Uni. Med. J.* 2010 67(10):724-730.

Rec#: 11880

Exclusion Codes: NRD, EXC

Ahn, S., W.Y. Kim, J.Y. Yoon, C.H. Sohn, D.W. Seo, S.H. Kim, S.B. Hong, C.M. Lim, Y.S. Koh, and W. Kim. Procalcitonin in 2009 H1N1 influenza pneumonia: Role in differentiating from bacterial pneumonia. *Tuberc. Respir. Dis.* 2010 68(4):205-211.

Rec#: 15470

Exclusion Codes: NRD, EXC

Aikawa, N., S. Fujishima, S. Endo, I. Sekine, K. Kogawa, Y. Yamamoto, S. Kushimoto, H. Yukioka, N. Kato, K. Totsuka, K. Kikuchi, T. Ikeda, K. Ikeda, K. Harada, and S. Satomura. Multicenter prospective study of procalcitonin as an indicator of sepsis. *J Infect Chemother* 2005 11(3):152-9.

Rec#: 3770

Exclusion Codes: NDE, EXC

Ali, A. M., M. A. Moaz, E. Ghoniem, T. Abd El Motaleb, and N. Sheri. Reliability of serum procalcitonin concentrations for the diagnosis of sepsis in neonates. *Egypt J Immunol* 2008 15(1):75-84.

Rec#: 2210

Exclusion Codes: NDE, EXC

Al-Nawas, B., I. Krammer, and P. M. Shah. Procalcitonin in diagnosis of severe infections. *Eur J Med Res* 1996 1(7):331-3.

Rec#: 6910

Exclusion Codes: NDE, EXC

Al-Nawas, B., and P. Shah. Procalcitonin in acute malaria. Eur J Med Res 1997 2(5):206-8.
Rec#: 6840
Exclusion Codes: SMN, EXC

al-Nawas, B., and P. M. Shah. Procalcitonin in patients with and without immunosuppression and sepsis. Infection 1996 24(6):434-6.
Rec#: 6890
Exclusion Codes: NDE, EXC

Ames, P. R., E. Walker, D. Aw, D. Marshall, F. de Villiers, and M. Staber. Multi-organ failure in adult onset Still's disease: a septic disguise. Clin Rheumatol 2009 28 Suppl 1:S3-6.
Rec#: 1360
Exclusion Codes: NDE, EXC

Amour, J., A. Birenbaum, O. Langeron, Y. Le Manach, M. Bertrand, P. Coriat, B. Riou, M. Bernard, and P. Hausfater. Influence of renal dysfunction on the accuracy of procalcitonin for the diagnosis of postoperative infection after vascular surgery. Crit Care Med 2008 36(4):1147-54.
Rec#: 1950
Exclusion Codes: NDE, EXC

Andermahr, J., A. Greb, T. Hensler, H. J. Helling, B. Bouillon, S. Sauerland, K. E. Rehm, and E. Neugebauer. Pneumonia in multiple injured patients: a prospective controlled trial on early prediction using clinical and immunological parameters. Inflamm Res 2002 51(5):265-72.
Rec#: 5300
Exclusion Codes: NDE, EXC

Anderson, R., and R. Schmidt. Clinical biomarkers in sepsis. Front Biosci (Elite Ed) 2010 2:504-20.
Rec#: 270
Exclusion Codes: NRD, EXC

Andreola, B., S. Bressan, S. Callegaro, A. Liverani, M. Plebani, and L. Da Dalt. Procalcitonin and C-reactive protein as diagnostic markers of severe bacterial infections in febrile infants and children in the emergency department. Pediatr Infect Dis J 2007 26(8):672-7.
Rec#: 8250
Exclusion Codes: NDE, EXC

Aouifi, A., V. Piriou, O. Bastien, P. Blanc, H. Bouvier, R. Evans, M. Celard, F. Vandenesch, R. Rousson, and J. J. Lehut. Usefulness of procalcitonin for diagnosis of infection in cardiac surgical patients. Crit Care Med 2000 28(9):3171-6.
Rec#: 6010
Exclusion Codes: NDE, EXC

Aouifi, A., V. Piriou, P. Blanc, H. Bouvier, O. Bastien, P. Chiari, R. Rousson, R. Evans, and J. J. Lehut. Effect of cardiopulmonary bypass on serum procalcitonin and C-reactive protein concentrations. Br J Anaesth 1999 83(4):602-7.
Rec#: 6260
Exclusion Codes: NRO, EXC

Apostolakis, E. E., C. Prokakis, and D. Dougenis. Are procalcitonin levels sufficient for the follow up of patients undergoing lung decortication for pleural empyema? Eur J Cardiothorac Surg 2009 35(1):193; author reply 194.
Rec#: 1220
Exclusion Codes: NDE, EXC

Arkader, R., E. J. Troster, M. R. Lopes, R. R. Junior, J. A. Carcillo, C. Leone, and T. S. Okay. Procalcitonin does discriminate between sepsis and systemic inflammatory response syndrome. Arch Dis Child 2006 91(2):117-20.

Rec#: 3560

Exclusion Codes: SMN, EXC

Assicot, M., D. Gendrel, H. Carsin, J. Raymond, J. Guilbaud, and C. Bohuon. High serum procalcitonin concentrations in patients with sepsis and infection. Lancet 1993 341(8844):515-8.

Rec#: 6930

Exclusion Codes: NRO, EXC

Atanasova, V., R. Rosmanova, and H. Andreeva. Procalcitonin: An innovative marker for bacterial infections. Biochemical, immunological and clinical aspects (chapter 2). Clin. Appl. Immunol. 2002 1(1):23-27.

Rec#: 14680

Exclusion Codes: NDE, EXC

Athhan, F., B. Akagunduz, F. Genel, M. Bak, and D. Can. Procalcitonin: a marker of neonatal sepsis. J Trop Pediatr 2002 48(1):10-4.

Rec#: 5490

Exclusion Codes: NDE, EXC

Ayazi, P., A. Mahyar, H.J. Hashemi, M.-M. Daneshi, T. Karimzadeh, and F. Salimi. Comparison of procalcitonin and C-reactive protein tests in children with urinary tract infection. Iran. J. Pediatr. 2009 19(4):381-386.

Rec#: 15670

Exclusion Codes: NDE, EXC

Aygun, C., O. Oran, and O. Portakal. Procalcitonin: Levels in newborns and as an indicator in the diagnosis of neonatal sepsis: Yenidoganlarda prokalsitonin duzeyleri ve sepsis tanisindaki yeri. Cocuk Sagligi Hast. Derg. 2003 46(2):83-89.

Rec#: 14410

Exclusion Codes: NRD, EXC

Azarpira, N., M. Ramzi, M. Aghdaie, and M. Daraie. Procalcitonin and C-reactive protein serum levels after hematopoietic stem-cell transplant. Exp Clin Transplant 2009 7(2):115-8.

Rec#: 580

Exclusion Codes: NDE, EXC

Aznar-Oroval, E., M. Sanchez-Yepes, P. Lorente-Alegre, M.C. San Juan-Gadea, B. Ortiz-Munoz, P. Prez-Ballester, I. Picn-Roig, and J. Maquez-Richart. Diagnostic value of procalcitonin, interleukin 8, interleukin 6, and c-reactive protein for detecting bacteremia and fungemia in cancer patients: Valor diagnostico de la procalcitonina, la interleucina 8, la interleucina 6 y la proteina C reactiva en la deteccin de bacteriemia y fungemia en pacientes con cancer. Enferm. Infect. Microbiol. Clin. 2010 28(5):273-277.

Rec#: 11510

Exclusion Codes: NDE, EXC

Balci, C., R. Sivaci, G. Akbulut, and H. S. Karabekir. Procalcitonin levels as an early marker in patients with multiple trauma under intensive care. J Int Med Res 2009 37(6):1709-17.

Rec#: 170

Exclusion Codes: NDE, EXC

Balci, C., H. Sungurtekin, E. Gurses, U. Sungurtekin, and B. Kaptanoglu. Usefulness of procalcitonin for diagnosis of sepsis in the intensive care unit. Crit Care 2003 7(1):85-90.

Rec#: 4970

Exclusion Codes: SMN, EXC

Ballot, D. E., O. Perovic, J. Galpin, and P. A. Cooper. Serum procalcitonin as an early marker of neonatal sepsis. S Afr Med J 2004 94(10):851-4.

Rec#: 4070

Exclusion Codes: NDE, EXC

Barati, M., F. Alinejad, M. A. Bahar, M. S. Tabrizi, A. R. Shamshiri, N. O. Bodouhi, and H. Karimi. Comparison of WBC, ESR, CRP and PCT serum levels in septic and non-septic burn cases. *Burns* 2008 34(6):770-4.

Rec#: 1600

Exclusion Codes: SMN, EXC

Bargues, L., Y. Chancerelle, J. Catineau, P. Jault, and H. Carsin. Evaluation of serum procalcitonin concentration in the ICU following severe burn. *Burns* 2007 33(7):860-4.

Rec#: 2710

Exclusion Codes: SMN, EXC

Barnes, C., V. Ignjatovic, F. Newall, J. Carlin, F. Ng, S. Hamilton, D. Ashley, K. Waters, and P. Monagle. Change in serum procalcitonin (δ PCT) predicts the clinical outcome of children admitted with febrile neutropenia. *Br J Haematol* 2002 118(4):1197-8.

Rec#: 5190

Exclusion Codes: SMN, EXC

Baruti Gafurri, Z., H. Pacarizi, B. Zhubi, L. Begolli, and V. Topciu. The importance of determining procalcitonin and C reactive protein in different stages of sepsis. *Bosn J Basic Med Sci* 2010 10(1):60-4.

Rec#: 150

Exclusion Codes: NRO, EXC

Basler, T., A. Meier-Hellmann, D. Bredle, and K. Reinhart. Amino acid imbalance early in septic encephalopathy. *Intensive Care Med* 2002 28(3):293-8.

Rec#: 5460

Exclusion Codes: SMN, EXC

Batard, E., N. Asseray, A. Kenzi, I. Gueffet, J.-L. Orsonneau, and G. Potel. Role of C-reactive protein and procalcitonin in the management of sepsis: Meningitis: Interet de la proteine C-reactive et de la procalcitonine dans la prise en charge des sepsis: L'exemple de la meningite. *Med. Ther.* 2003 9(1-2):26-31.

Rec#: 14500

Exclusion Codes: NRD, EXC

Baumgarten, R., N.C.V. Pequeriaux, M.J.E. Van Puyenbroek, and B. Speelberg. Diagnosis of sepsis by procalcitonin: Is procalcitonine van additionele waarde bij de diagnostiek van sepsis? *Ned. Tijdschr. Klin. Chem.* 2002 27(1):32-35.

Rec#: 14670

Exclusion Codes: NRD, EXC

Baykut, D., J. Schulte-Herbruggen, and A. Krian. The value of procalcitonin as an infection marker in cardiac surgery. *Eur J Med Res* 2000 5(12):530-6.

Rec#: 5910

Exclusion Codes: NRO, EXC

Baylan, O., A. Balkan, A. Inal, O. Kisa, A. Albay, L. Doganci, and C. H. Acikel. The predictive value of serum procalcitonin levels in adult patients with active pulmonary tuberculosis. *Jpn J Infect Dis* 2006 59(3):164-7.

Rec#: 8770

Exclusion Codes: NDE, EXC

Becker, K. L., R. Snider, and E. S. Nylen. Procalcitonin assay in systemic inflammation, infection, and sepsis: clinical utility and limitations. *Crit Care Med* 2008 36(3):941-52.

Rec#: 1870

Exclusion Codes: NRD, EXC

Becker, K. L., R. Snider, and E. S. Nylen. Procalcitonin in sepsis and systemic inflammation: a harmful biomarker and a therapeutic target. *Br J Pharmacol* 2010 159(2):253-64.

Rec#: 300

Exclusion Codes: NDE, EXC

Beghetti, M., P. C. Rimensberger, A. Kalangos, W. Habre, and A. Gervaix. Kinetics of procalcitonin, interleukin 6 and C-reactive protein after cardiopulmonary-bypass in children. *Cardiol Young* 2003 13(2):161-7.

Rec#: 9870

Exclusion Codes: NRO, EXC

Bell, K., M. Wattie, K. Byth, R. Silvestrini, P. Clark, E. Stachowski, and E. M. Benson. Procalcitonin: a marker of bacteraemia in SIRS. *Anaesth Intensive Care* 2003 31(6):629-36.

Rec#: 4500

Exclusion Codes: NDE, EXC

Bellmann-Weiler, R., M. Ausserwinkler, K. Kurz, I. Theurl, and G. Weiss. Clinical potential of C-reactive protein and procalcitonin serum concentrations to guide differential diagnosis and clinical management of pneumococcal and Legionella pneumonia. *J. Clin. Microbiol.* 2010 48(5):1915-1917.

Rec#: 15440

Exclusion Codes: NDE, EXC

Benador, N., C. A. Siegrist, D. Gendrel, C. Greder, D. Benador, M. Assicot, C. Bohuon, and E. Girardin.

Procalcitonin is a marker of severity of renal lesions in pyelonephritis. *Pediatrics* 1998 102(6):1422-5.

Rec#: 10720

Exclusion Codes: SMN, EXC

Bender, L., J. Thaarup, K. Varming, H. Krarup, S. Ellermann-Eriksen, and F. Ebbesen. Early and late markers for the detection of early-onset neonatal sepsis. *Dan Med Bull* 2008 55(4):219-23.

Rec#: 1040

Exclusion Codes: NDE, EXC

Benhamou, D. Optimal duration of antibiotic therapy in community acquired pneumonia: Durees optimales de l'antibiotherapie dans les pneumonies communautaires. *Rev. Mal. Respir.* 2009 26(4):458-460.

Rec#: 12380

Exclusion Codes: NDE, EXC

Benitz, W.E. Adjunct laboratory tests in the diagnosis of early-onset neonatal sepsis. *Clin. Perinatol.* 2010 37(2):421-438.

Rec#: 11410

Exclusion Codes: NDE, EXC

Benoist, J. F., O. Mimoz, M. Assicot, and A. Edouard. Serum procalcitonin, but not C-reactive protein, identifies sepsis in trauma patients. *Clin Chem* 1998 44(8 Pt 1):1778-9.

Rec#: 6720

Exclusion Codes: NDE, EXC

Beovic, B., S. Kreft, J. Osredkar, D. Kese, and B. Bonac-Tuma. Serum procalcitonin levels in patients with mild community-acquired pneumonia. *Clin Microbiol Infect* 2005 11(12):1050-1.

Rec#: 8990

Exclusion Codes: NRO, EXC

Berger, C., S. Schwarz, W. R. Schaebitz, A. Aschoff, and S. Schwab. Serum procalcitonin in cerebral ventriculitis. *Crit Care Med* 2002 30(8):1778-81.

Rec#: 5220

Exclusion Codes: SMN, EXC

Bergmann, A., and C. Bohuon. Decrease of serum dipeptidylpeptidase activity in severe sepsis patients: relationship to procalcitonin. *Clin Chim Acta* 2002 321(1-2):123-6.

Rec#: 5320

Exclusion Codes: NRO, EXC

Bernard, L., F. Ferriere, P. Casassus, F. Malas, S. Leveque, L. Guillevin, and O. Lortholary. Procalcitonin as an early marker of bacterial infection in severely neutropenic febrile adults. *Clin Infect Dis* 1998 27(4):914-5.

Rec#: 6640

Exclusion Codes: NDE, EXC

Bernstein, L.H., A. Devakonda, E. Engelman, G. Pancer, J. Ferrara, J. Rucinski, S. Raoof, L. George, and L. Melniker. The role of procalcitonin in the diagnosis of sepsis and patient assignment to medical intensive care. *J. Clin. Ligand Assay* 2007 30(3-4):98-104.

Rec#: 13240

Exclusion Codes: NDE, EXC

Bewick, T., and W.S. Lim. Diagnosis of community-acquired pneumonia in adults. *Expert Rev. Respir. Med.* 2009 3(2):153-164.

Rec#: 15790

Exclusion Codes: NDE, EXC

Bhatia, B. D., and S. Basu. Newer diagnostic tests for bacterial diseases. *Indian J Pediatr* 2007 74(7):673-7.

Rec#: 8310

Exclusion Codes: NDE, EXC

Bignardi, G. E., R. Dhar, R. Heycock, S. Bansal, and N. Majmudar. Can procalcitonin testing reduce antibiotic prescribing for respiratory infections? *Age Ageing* 2006 35(6):625-6.

Rec#: 8730

Exclusion Codes: NDE, EXC

Billeter, A., M. Turina, B. Seifert, L. Mica, R. Stocker, and M. Keel. Early serum procalcitonin, interleukin-6, and 24-hour lactate clearance: useful indicators of septic infections in severely traumatized patients. *World J Surg* 2009 33(3):558-66.

Rec#: 1080

Exclusion Codes: NDE, EXC

Bistrian, B. R. Acute phase proteins and the systemic inflammatory response. *Crit Care Med* 1999 27(3):452-3.

Rec#: 6550

Exclusion Codes: NDE, EXC

Bitkover, C. Y., L. O. Hansson, G. Valen, and J. Vaage. Effects of cardiac surgery on some clinically used inflammation markers and procalcitonin. *Scand Cardiovasc J* 2000 34(3):307-14.

Rec#: 6070

Exclusion Codes: NRO, EXC

Blijlevens, N. M., J. P. Donnelly, J. F. Meis, M. H. De Keizer, and B. E. De Pauw. Procalcitonin does not discriminate infection from inflammation after allogeneic bone marrow transplantation. *Clin Diagn Lab Immunol* 2000 7(6):889-92.

Rec#: 10480

Exclusion Codes: NDE, EXC

Blommendahl, J., M. Janas, S. Laine, A. Miettinen, and P. Ashorn. Comparison of procalcitonin with CRP and differential white blood cell count for diagnosis of culture-proven neonatal sepsis. *Scand J Infect Dis* 2002 34(8):620-2.

Rec#: 5120

Exclusion Codes: NDE, EXC

Boeken, U., P. Feindt, M. Micek, T. Petzold, H. D. Schulte, and E. Gams. Procalcitonin (PCT) in cardiac surgery: diagnostic value in systemic inflammatory response syndrome (SIRS), sepsis and after heart transplantation (HTX). *Cardiovasc Surg* 2000 8(7):550-4.

Rec#: 5980

Exclusion Codes: NDE, EXC

Boeken, U., P. Feindt, E. Mohan, Th. Petzold, M. Micek, and E. Gams. The influence of extracorporeal circulation and inflammatory responses such as SIRS and sepsis on secretion of procalcitonin (PCT). *J. Clin. Basic Cardiol.* 1999 2(2):225-227.

Rec#: 15020

Exclusion Codes: SMN, EXC

Boeken, U., P. Feindt, T. Petzold, M. Klein, M. Micek, U. T. Seyfert, E. Mohan, H. D. Schulte, and E. Gams. Diagnostic value of procalcitonin: the influence of cardiopulmonary bypass, aprotinin, SIRS, and sepsis. *Thorac Cardiovasc Surg* 1998 46(6):348-51.

Rec#: 6590

Exclusion Codes: NRO, EXC

Bogar, L., Z. Molnar, P. Kenyeres, and P. Tarsoly. Sedimentation characteristics of leucocytes can predict bacteraemia in critical care patients. *J Clin Pathol* 2006 59(5):523-5.

Rec#: 3410

Exclusion Codes: SMN, EXC

Bogar, L., Z. Molnar, P. Tarsoly, P. Kenyeres, and S. Marton. Serum procalcitonin level and leukocyte antisedimentation rate as early predictors of respiratory dysfunction after oesophageal tumour resection. *Crit Care* 2006 10(4):R110.

Rec#: 3240

Exclusion Codes: SMN, EXC

Bollu, M., A. C. Marte-Grau, and R. K. Bobba. Procalcitonin-guided antibiotic use in acute respiratory tract infections. *Arch Intern Med* 2009 169(7):716.

Rec#: 7450

Exclusion Codes: NDE, EXC

Bonac, B., M. Derganc, B. Wraber, and S. Hojker. Interleukin-8 and procalcitonin in early diagnosis of early severe bacterial infection in critically ill neonates. *Pflugers Arch* 2000 440(5 Suppl):R72-4.

Rec#: 6020

Exclusion Codes: NDE, EXC

Boo, N. Y., A. A. Nor Azlina, and J. Rohana. Usefulness of a semi-quantitative procalcitonin test kit for early diagnosis of neonatal sepsis. *Singapore Med J* 2008 49(3):204-8.

Rec#: 1990

Exclusion Codes: NDE, EXC

Bossink, A. W., A. B. Groeneveld, and L. G. Thijs. Prediction of microbial infection and mortality in medical patients with fever: plasma procalcitonin, neutrophilic elastase-alpha1-antitrypsin, and lactoferrin compared with clinical variables. *Clin Infect Dis* 1999 29(2):398-407.

Rec#: 6420

Exclusion Codes: NDE, EXC

Bota, D. P., M. Van Nuffelen, A. N. Zakariah, and J. L. Vincent. Serum levels of C-reactive protein and procalcitonin in critically ill patients with cirrhosis of the liver. *J Lab Clin Med* 2005 146(6):347-51.

Rec#: 3570

Exclusion Codes: NDE, EXC

Bottner, F., A. Wegner, W. Winkelmann, K. Becker, M. Erren, and C. Gotze. Interleukin-6, procalcitonin and TNF-alpha: markers of peri-prosthetic infection following total joint replacement. *J Bone Joint Surg Br* 2007 89(1):94-9.
Rec#: 2970

Exclusion Codes: SMN, EXC

Bouadma, L., C.-E. Luyt, F. Tubach, J. Chastre, and M. Wolff. Procalcitonin in intensive care units: the PRORATA trial - Authors' reply. *Lancet* 2010 375(9726):1606-1607.

Rec#: 11430

Exclusion Codes: NDE, EXC

Bouros, D., and S. Anevlavis. Scoring systems in community acquired pneumonia. *Pneumon* 2009 22(4).

Rec#: 12070

Exclusion Codes: NRD, EXC

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Exclusion Codes: NRO, EXC

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Clec'h, C., F. Ferriere, P. Karoubi, J. P. Fosse, M. Cupa, P. Hoang, and Y. Cohen. Diagnostic and prognostic value of procalcitonin in patients with septic shock. *Crit Care Med* 2004 32(5):1166-9.

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Rec#: 9910

Exclusion Codes: NDE, EXC

Kotoula, A., S. Gardikis, A. Tsalkidis, E. Mantadakis, A. Zissimopoulos, S. Deftereos, G. Tripsianis, K. Manolas, A. Chatzimichael, and G. Vaos. Comparative efficacies of procalcitonin and conventional inflammatory markers for prediction of renal parenchymal inflammation in pediatric first urinary tract infection. *Urology* 2009 73(4):782-6.

Rec#: 7590

Exclusion Codes: SMN, EXC

Kotoula, A., S. Gardikis, A. Tsalkidis, E. Mantadakis, A. Zissimopoulos, S. Deftereos, G. Tripsianis, K. Manolas, A. Chatzimichael, and G. Vaos. Comparative Efficacies of Procalcitonin and Conventional Inflammatory Markers for Prediction of Renal Parenchymal Inflammation in Pediatric First Urinary Tract Infection. *Urology* 2009 73(4):782-786.

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Exclusion Codes: NDE, EXC

Kotoula, A., S. Gardikis, A. Tsalkidis, E. Mantadakis, A. Zissimopoulos, K. Kambouri, S. Deftereos, G. Tripsianis, K. Manolas, A. Chatzimichael, and G. Vaos. Procalcitonin for the early prediction of renal parenchymal involvement in children with UTI: preliminary results. *Int Urol Nephrol* 2009 41(2):393-9.

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Rec#: 2530

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Rec#: 8470

Exclusion Codes: NDE, EXC

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Exclusion Codes: NRO, EXC

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Exclusion Codes: NRO, EXC

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Exclusion Codes: NDE, EXC

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Snider, R. H. Jr, E. S. Nylen, and K. L. Becker. Procalcitonin and its component peptides in systemic inflammation: immunochemical characterization. *J Investig Med* 1997 45(9):552-60.

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Rec#: 15770

Exclusion Codes: NDE, EXC

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Rec#: 15110

Exclusion Codes: NDE, EXC

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Rec#: 9050

Exclusion Codes: NRO, EXC

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Rec#: 2190

Exclusion Codes: NDE, EXC

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Rec#: 16820

Exclusion Codes: NDE, EXC

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Rec#: 10500

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Exclusion Codes: NDE, EXC

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Rec#: 14400

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Rec#: 6180

Exclusion Codes: NDE, EXC

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Rec#: 12020

Exclusion Codes: NRD, EXC

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Rec#: 11290

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Exclusion Codes: NDE, EXC

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Rec#: 4410

Exclusion Codes: SMN, EXC

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Rec#: 3610

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Rec#: 2280

Exclusion Codes: NRD, EXC

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Rec#: 12410

Exclusion Codes: NDE, EXC

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Exclusion Codes: NDE, EXC

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Rec#: 14800

Exclusion Codes: NDE, EXC

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Exclusion Codes: NRO, EXC

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Exclusion Codes: NDE, EXC

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Exclusion Codes: NDE, EXC

Zakariah, A. N., S. M. Cozzi, M. Van Nuffelen, C. M. Clausi, O. Pradier, and J. L. Vincent. Combination of biphasic transmittance waveform with blood procalcitonin levels for diagnosis of sepsis in acutely ill patients. *Crit Care Med* 2008 36(5):1507-12.

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Zazula, R., M. Prucha, A. Spaleny, M. Jaresova, and S. Vitko. Procalcitonin not only in the differential diagnosis of the inflammatory response: Prokalcitonin nejen v diferencialni diagnostice zanetlive odpovedi organismu. Anesteziol. Neodkladna Pece 2002 13(2):86-91.

Rec#: 14640

Exclusion Codes: NRD, EXC

Zeglen, S., J. Wojarski, E. Wozniak-Grygiel, M. Siola, M. Szewczyk, E. Kucewicz-Czech, J. Nozynski, and M. Zembala. Procalcitonin serum concentration during *Pneumocystis jiroveci* colonization or *Pseudomonas aeruginosa* infection/colonization in lung transplant recipients. Transplant Proc 2009 41(8):3225-7.

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Exclusion Codes: NRO, EXC

Zeitoun, A. A., S. S. Gad, F. M. Attia, A. S. Abu Maziad, and E. F. Bell. Evaluation of neutrophilic CD64, interleukin 10 and procalcitonin as diagnostic markers of early- and late-onset neonatal sepsis. Scand J Infect Dis 2010 42(4):299-305.

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Exclusion Codes: NDE, EXC

Zhang, D., T. Lavaux, A. C. Voegeli, T. Lavigne, V. Castelain, N. Meyer, R. Sapin, D. Aunis, M. H. Metz-Boutigue, and F. Schneider. Prognostic value of chromogranin A at admission in critically ill patients: a cohort study in a medical intensive care unit. Clin Chem 2008 54(9):1497-503.

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Zycinska, K., K. A. Wardyn, T. M. Zielonka, P. Tyszko, and M. Straburzynski. Procalcitonin as an indicator of systemic response to infection in active pulmonary Wegener's granulomatosis. J Physiol Pharmacol 2008 59 Suppl 6:839-44.

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Exclusion Codes: NRO, EXC

APPENDIX C. Abstraction Tables

Evidence Table 1A. Study Description Table for Bouadma et al., 2010.¹

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Bouadma et al., 2010. PRORATA (procalcitonin to reduce antibiotic treatments in acutely ill patients) Country, institution type: France, 5 university-affiliated hospitals Enrollment period: 06/07 – 05/08 Funding: Assistance Publique-Hôpitaux de Paris, France, and Brahm's, Germany Author industry relationship disclosures: 4 authors disclosed conflicts	Design: RCT; 1:1, masked until randomization, stratified by center Superior for antibiotics free days Interventions: G1: PCT-guided antibiotic therapy G2: Standard antibiotic therapy Presenting condition: Critically ill patients, suspected bacterial infection on admission to ICU or during stay Setting: ICU (5 MICU, 2 SICU) N screened, reasons for exclusion N at enrollment: G1: 311 G2: 319 N at follow-up: G1: 307	Primary outcome: Mortality at days 28 and 60 (non-inferiority analysis), and number of days without antibiotics by day 28 (superiority analysis) 90 % power to detect a 3 day increase in days without antibiotics, 133 subjects per study group. To have 80 % chance of non-inferiority with respect to mortality (10 % alpha risk), 300 patients needed per study arm Secondary outcomes: ABT exposure, morbidity Assay type: Kryptor PCT, Brahm's Decision-making: 2 interventions For antibiotic initiation G1: PCT < 0.25 antibiotics strongly discouraged; PCT ≥ 0.25, < 0.5 antibiotics discouraged; PCT ≥ 0.5 and < 1,	Inclusion criteria: <ul style="list-style-type: none"> Critically ill patients ICU Suspected bacterial infection Exclusion criteria: <ul style="list-style-type: none"> Age < 18 years Antibiotics > 24 hours before enrollment Pregnancy Expected ICU stay < 3 days Stem cell transplantation ANC < 500 Chronic infections SAPS II > 65 (unlikely to survive) Do not resuscitate 	Age, years: [mean (SD), median (range/IQR)] G1: 61.0 (15.2) G2: 62.1 (15.0) [<i>test, result (p-value, 95% CI)</i>] G1: 16 (5 %) G2: 13 (4 %) G1/G2: Women, n (%): G1: 100 (33 %) G2: 110 (35 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: PCT: [mean (SD), median (range/IQR)] G1: 12.0 (30.9) G2: 12.0 (32.6) [<i>test, result (p-value, 95% CI)</i>] G1/G2: Infection site, n (%): G1: Pulmonary (183) 71 % UTI (24) 9 % SSI (5) 2 % Intra-abdominal (14) 5 % CNS (7) 2 % CVC (5) 3 % Bacteremia (9) 4 % Other (11) 4 % G1/G2: CRF on hemodialysis, n (%): G1: 17 (6 %) G2: 11 (4 %) [<i>test, result (p-value, 95% CI)</i>]	CHF (NYHA III/IV), n (%): [<i>test, result (p-value, 95% CI)</i>] G1: 16 (5 %) G2: 13 (4 %) G1/G2: Insulin-dependent diabetes, n (%): G1: 27 (9 %) G2: 22 (7 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: Cirrhosis, n (%): G1: 20 (7 %) G2: 13 (4 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: Home oxygen, n (%): G1: 23 (7 %) G2: 18 (6 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: CRF on hemodialysis, n (%): G1: 17 (6 %) G2: 11 (4 %) [<i>test, result (p-value, 95% CI)</i>]

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics																								
	<p>G2: 314</p> <p>Average follow-up, days: [mean (SD), median (range/IQR)]</p> <p>G1: G2: Follow-up to 60 days</p>	<p>antibiotics encouraged; PCT \geq 1.0, antibiotics strongly encouraged</p> <p>G2: Standard therapy</p> <p>For antibiotic discontinuation</p> <p>G1: PCT < 0.25, stopping antibiotics strongly encouraged; PCT \geq 80 % decrease from peak or < 0.5 ng/mL, stopping antibiotics encouraged; PCT < 80 % decrease from peak or \geq 0.5, continuing antibiotics encouraged; PCT > baseline and \geq 0.5, continuing antibiotics strongly encouraged</p> <p>G2: Standard therapy</p> <p>Condition = definition: Suspected bacterial infections</p> <p>Condition = definition: Sepsis</p>		<p>G2:</p> <table> <tr><td>Pulmonary</td><td>(211)</td><td>71 %</td></tr> <tr><td>UTI</td><td>(18)</td><td>9 %</td></tr> <tr><td>SSI</td><td>(6)</td><td>2 %</td></tr> <tr><td>Intra-abdominal</td><td>(20)</td><td>5 %</td></tr> <tr><td>CNS</td><td>(6)</td><td>2 %</td></tr> <tr><td>CVC</td><td>(3)</td><td>3 %</td></tr> <tr><td>Bacteremia</td><td>(11)</td><td>4 %</td></tr> <tr><td>Other</td><td>(9)</td><td>4 %</td></tr> </table>	Pulmonary	(211)	71 %	UTI	(18)	9 %	SSI	(6)	2 %	Intra-abdominal	(20)	5 %	CNS	(6)	2 %	CVC	(3)	3 %	Bacteremia	(11)	4 %	Other	(9)	4 %	<p>[CI])</p> <p>G1/G2:</p> <p>Metastatic cancer, n (%):</p> <p>G1: 8 (3 %) G2: 5 (2 %)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2:</p> <p>Immunocompromised, n (%):</p> <p>G1: 47 (15 %) G2: 51 (16 %)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2:</p> <p>SAPS II, mean (std dev):</p> <p>G1: 47.1 (17.9) G2: 46.9 (17.2)</p> <p>SOFA, mean (std dev):</p> <p>G1: 8.0 (4.7) G2: 7.7 (4.6)</p> <p>Septic shock, n (%):</p> <p>G1: 53 (17 %) G2: 55 (18 %)</p>
Pulmonary	(211)	71 %																											
UTI	(18)	9 %																											
SSI	(6)	2 %																											
Intra-abdominal	(20)	5 %																											
CNS	(6)	2 %																											
CVC	(3)	3 %																											
Bacteremia	(11)	4 %																											
Other	(9)	4 %																											

Evidence Table 2 A. Intermediate Outcomes for Bouadma et al., 2010.¹

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
<p>Days without antibiotics at 28 days (superiority): [mean (SD), median (range/IQR)] G1: 14.3 (9.1) G2: 11.6 (8.2) [<i>test, result (p-value, 95% CI)</i>] p < 0.0001 G1/G2:</p> <p>Duration of first episode antibiotic treatment, mean (std dev): G1: 6.1 (6.0) G2: 9.9 (7.1) [<i>test, result (p-value, 95% CI)</i>] p < 0.0001 G1/G2:</p> <p>Days antibiotic exposure/1,000: (rate days exposed per #patient-days) G1: 653 G2: 812 [<i>test, result (p-value, 95% CI)</i>] G1/G2: -159(-185 to -131)</p>	NR	NR	<p>Days: [mean (SD), median (range/IQR)] G1: 26.1 (19.3) G2: 26.4 (18.3) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p>	<p>Days: [mean (SD), median (range/IQR)] G1: 15.9 (16.1) G2: 14.4 (14.1) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p>

Evidence Table 3A. Morbidity Outcomes for Bouadma et al., 2010.¹

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
<p>SOFA day 28, mean (std dev): G1: 1.5 (3.0) G2: 0.9 (2.4) [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p>	<p>Mechanical ventilation-free days: [mean (SD), median (range/IQR)] G1: 16.2 (11.1) G2: 16.9 (10.9) [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p> <p>Nosocomial superinfection, n, (%): G1: 106 (34.5 %) G2: 97 (30.9 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p> <p>Multi drug resistant, n (%): G1: 55 (17.9 %) G2: 52 (16.6 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p>	<p>Relapse, n, (%): G1: 20 (6.5 %) G2: 16 (5.1 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p>	NR	NR

Evidence Table 4A. Mortality Outcomes for Bouadma et al., 2010.¹

In-hospital mortality	28-day mortality	60-day mortality	Pneumonia-related death	Proportion surviving hospitalization
NR	Proportion (%): G1: 21.2 % G2: 20.4 % [test, result (p-value, 95% CI)] G1/G2: Non-inferiority, 10 % margin	Proportion (%): G1: 30.0 % G2: 26.1 % [test, result (p-value, 95% CI)] G1/G2: Non-inferiority, 10 % margin	NR	NR

Evidence Table 5A. Function and Quality of Life Outcomes for Bouadma et al., 2010.¹

Days ≤ 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score
NR	NR	NR	NR

Evidence Table 6A. Adverse Effects, Adherence for Bouadma et al., 2010.¹

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence
NR	NR	NR	NR

Evidence Table 7A. Randomized Trial Study Quality Ratings for Bouadma et al., 2010.¹

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results
Y	Y	Y	Y	Y	Y	Y

Evidence Table 1B. Study Description Table for Briel et al., 2008.²

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Briel et al., 2008. Country, institution type: Switzerland Enrollment period: December 13, 2004-April 30, 2006 Funding: Swiss National Science Foundation; Assoc. for the Promotion of Science and Postgraduate Training of the University Hospital of Basel; Brahms Author industry relationship disclosures: 1 author consultant and recipient of funds from Brahms for travel, speaking	Design: RCT, open, multicenter, non-inferiority Interventions: G1: G2: Presenting condition: Adults with acute respiratory tract infection in need of antibiotics Setting: 53 primary care physicians, multi-center, non-inferiority trial, monitored by independent monitoring board 8162 patients consulted for RTI 1480 assessed because of perceived need for antibiotics 1022 excluded 67 with symptoms > 28 days 21 given antibiotics within 28 days 180 not fluent 41 psych issues 35 needed immediate hospitalization 63 with severe immunosuppression 152 not available for follow-up	Primary outcome: Intent to treat and per protocol Primary outcomes Number of days in first 14 days after baseline with restricted activities due to RTI Intent to treat and per protocol Secondary outcomes: Only per protocol analysis Antibiotic prescription rate Duration of antibiotic Discomfort scale Days of work missed Days with adverse medication effects Ongoing or relapsed RTI SAEs within 28 days 275 needed to show that at worst PCT-guided therapy increased antibiotic duration by 1 day, alpha error 5 %	Inclusion criteria: <ul style="list-style-type: none"> Cold Sinusitis Pharyngitis Tonsillitis, Tracheobronchitis AECOPD, CAP Intention to prescribe antibiotics Exclusion criteria: <ul style="list-style-type: none"> Antibiotics in previous 28 days Psych disorders Severe immunosuppression Cystic fibrosis TB Need for immediate hospitalization Not available for follow-up Not fluent in German 	Age, years: [mean (SD), G1: 48 (18) G2: 48 (18) [test, result (p-value, 95% CI)] G1/G2: NSS Men, n (%): G1: 98 (42 %) G2: 87 (38 %) [test, result (p-value, 95% CI)] G1/G2: NSS Days with restricted activities, mean (SD): G1: 5.8 (4.7) G2: 6.5 (4.7) [test, result (p-value, 95% CI)] G1/G2: NSS Discomfort score, mean (SD): G1: 6.1 (2.6) G2: 6.2 (2.4) [test, result (p-value, 95% CI)] G1/G2: NSS Diagnosis Common cold, n, (%): G1: 13 (5.6 %) G2: 18 (8.0 %) [test, result (p-value, 95% CI)] G1/G2: NSS Other, n (%): G1: 7 (3.0 %) G2: 10 (4.4 %) [test, result (p-value, 95% CI)] G1/G2: NSS Acute sinusitis, n, (%): G1: 52 (22 %)	Any co-morbidities, n (%): [test, result (p-value, 95% CI)] G1: 33 (14 %) G2: 37 (16 %) G1/G2: NSS Chronic lung disease, n (%): [test, result (p-value, 95% CI)] G1: 12 (5.2 %) G2: 14 (6.2 %) G1/G2: NSS Diabetes mellitus, n (%): G1: 6 (2.6 %) G2: 7 (3.1 %) [test, result (p-value, 95% CI)] G1/G2: NSS Congestive heart failure, n (%): G1: 8 (3.4 %) G2: 6 (2.6 %) [test, result (p-value, 95% CI)] G1/G2: NSS PCT, mean (SD): G1: 0.39 (2.7)

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
	<p>217 physician not able to follow 246 refused consent</p> <p>458 randomized</p> <p>N at enrollment: G1: 232 G2: 226</p> <p>N at follow-up: G1: 230 (2 LTFU) G2: 223 (2 LTFU)</p> <p>Average follow-up, days: [mean (SD), median (range/IQR)] G1: 28 days G2: 28 days</p>	<p>2-4 hours</p> <p>Decision-making: G1: For PCT 0.01, antibiotics discouraged For PCT between 0.1-0.25, antibiotics not recommended For PCT > 0.25, antibiotics recommended Also if second PCT in 6-24 hours was increased by 50 %</p> <p>G2:</p> <p>Decision-making: G1: If PCT < 0.25 at day 3, discontinuation recommended</p> <p>Condition = definition: Physician diagnosis</p>		<p>G2: 52 (23 %) [test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>Pharyngitis/tonsillitis, n, (%): G1: 42 (18 %) G2: 33 (15 %) [test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>Laryngitis/tracheitis, n, (%): G1: 8 (3.5 %) G2: 4 (1.8 %) [test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>Acute otitis media, n, (%): G1: 0 G2: 5 (2.2 %) [test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>Acute bronchitis, n, (%): G1: 58 (25 %) G2: 70 (31 %) [test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>Influenza, n, (%): G1: 3 (1.3 %) G2: 1 (0.4 %) [test, result (p-value, 95% CI)]</p>	<p>G2: 0.25 (1.3) [test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>CRP, mean (SD): G1: 51 (65) G2: 51 (55) [test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p>

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
				<p>Cl])</p> <p>G1/G2: NSS</p> <p>AECOPD, n, (%):]</p> <p>G1: 12 (5.2 %)</p> <p>G2: 9 (4.0 %)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>Acute asthma attack, n, (%):]</p> <p>G1: 6 (2.6 %)</p> <p>G2: 2 (1.3 %)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>CAP, n, (%):]</p> <p>G1: 38 (16 %)</p> <p>G2: 31 (14 %)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p>	

Evidence Table 2 B. Intermediate Outcomes for Briel et al., 2008.²

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
<p>Days with antibiotics: mean (SD)</p> <p>G1: 6.2 (2.5)</p> <p>G2: 7.1 (2.2)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2:</p> <p>Adjusted difference in days (95 % CI) -1.0 (-1.7 to -0.4)</p>	<p>Any antibiotic use, antibiotic prescription rate (%):</p> <p>G1: 58 (25 %)</p> <p>G2: 219 (97 %)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2:</p> <p>Difference -72 % (-78 to -66)</p> <p>Adjusted odds ratio (95 % CI) 0.01 (0.002 to 0.02)</p>	NR	NR	NR

Evidence Table 3B. Morbidity Outcomes for Briel et al., 2008.²

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
NR	Intent to treat Restricted activities, days: [mean (SD), median (range/IQR)] G1: 8.7 (3.9) G2: 8.6 (3.0) [<i>test, result (p-value, 95% CI)</i>] G1/G2: Adjusted difference (95 % CI) 0.2 (-0.4 to 0.9) Days of work missed within 14 days: [mean (SD), median (range/IQR)] G1: 4.9 (4.6) G2: 4.8 (4.2) [<i>test, result (p-value, 95% CI)</i>] G1/G2: Adjusted difference (95 % CI) 0.3 (-0.6 to 1.2)	NR	NR	RTI symptoms at 28 days (%): G1: 69 (30 %) G2: 67 (30 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS Degree of discomfort score at 14 days: [mean (SD)] G1: 1.9 (2.7) G2: 1.1 (1.9) [<i>test, result (p-value, 95% CI)</i>] G1/G2: Adjusted difference (95 % CI) 0.8 (0.4 to 1.2)

Evidence Table 4B. Mortality Outcomes for Briel et al., 2008.²

In-hospital mortality	28-day mortality	Death	Pneumonia-related death	Proportion surviving hospitalization
NR	NR	NR	NR	NR

Evidence Table 5B. Function and Quality of Life Outcomes for Briel et al., 2008.²

Days ≤ 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score
NR	NR	NR	NR

Evidence Table 6B. Adverse Effects and Adherence for Briel et al., 2008.²

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence
Proportion (%): G1: G2: [<i>test, result (p-value, 95% CI)</i>] G1/G2:	Days of AEs within 14 days: [mean (SD), median (range/IQR)] G1: 2.3 (4.6) G2: 3.6 (6.1) [<i>test, result (p-value, 95% CI)</i>] G1/G2: Adjusted difference (95 % CI) -1.1 (-2.1 to -0.1) Mainly due to number with diarrhea (47/231 vs 76/224)	NR	NR

Evidence Table 7B. Randomized Trial Study Quality Ratings for Briel et al., 2008.²

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results
Y- balanced Y-concealment	Y	Y	Y	Y	Y	Y

Evidence Table 1C. Study Description Table for Burkhardt et al., 2010.³

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Burkhardt et al., 2010. Country, institution type: Germany, Medical Hospital Hannover Enrollment period: Not given Funding: Not given Author industry relationship disclosures: Conflicts for 7 authors available at www.erj.ersjournals.com/misc/statements.dtl , 3 authors from Brahms Research Dept.	Design: RCT, intent to treat analysis Interventions: G1: PCT-guided antibiotic therapy G2: Control Presenting condition: Acute respiratory tract infection Setting: Primary care offices N at enrollment: G1: 275 G2: 275 N at follow-up: G1: G2: Average follow-up, days: [mean (SD), median (range/IQR)] G1: 14 day G2: 28 day	Primary outcome: Number of days with significant health impairment due to RTI at day 14 Non-inferior of the 95 % CI for the difference between groups in number of days with impairment was < 1 day 90 % chance to show that PCT-guided therapy does not lead to > 1 additional day of impairment with 275 patients per group Secondary outcomes: Prescription rate, duration of antibiotic, days with antibiotic-associated SEs, symptoms on day 14 and 28, revisit within 28 days, change of antibiotics within 28 days, hospitalization within 28 days, 28 day mortality	Inclusion criteria: <ul style="list-style-type: none"> > 18 years of age Symptoms of acute RTI, URTI or LRTI-no standardized clinical diagnosis Exclusion criteria: <ul style="list-style-type: none"> Antibiotics in previous 2 weeks Major surgery in past 4 weeks Chronic liver disease Autoimmune or systemic disorders HD Medullary thyroid cancer Inflammatory diseases 	Age, years: [mean (SD), median (range/IQR)] G1: 41.4 ±15.3 G2: 43.4 ±15.5 [test, result (p-value, 95% CI)] G1/G2: NSS Male, n (%): G1: 164 (59.6) G2: 161 (58.5) [test, result (p-value, 95% CI)] G1/G2: NSS PCT : [mean (SD), median (range/IQR)] G1: 0.054 ng/mL G2: 0.057 ng/mL [test, result (p-value, 95% CI)] G1/G2: NSS	Insulin-dependent diabetes, n (%): G1: 15/275 (5.5 %) G2: 9/275 (3.3 %) [test, result (p-value, 95% CI)] G1/G2: NSS Congestive heart failure, n (%): G1: 5/275 (1.8 %) G2: 5/275 (1.8 %) [test, result (p-value, 95% CI)] G1/G2: NSS COPD, n (%): G1: 4/275 (1.5 %) G2: 9/275 (3.3 %) [test, result (p-value, 95% CI)] G1/G2: NSS

		<p>Kruskal-Wallis and Pearson's Chi-squared test</p> <p>Assay type: Brahms Kryptor PCT</p> <p>Decision-making: G1: PCT < 0.25, no antibiotics; PCT \geq 0.25, antibiotics recommended G2: Standard care</p>		
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Evidence Table 2 C. Intermediate Outcomes for Burkhardt et al., 2010.³

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
Days: [mean (SD), median (range/IQR)] G1: 7.8 ± 2.8 G2: 7.7 ± 3.3 [<i>test, result (p-value, 95% CI)</i>] G1/G2: $p = 0.68$	Any antibiotic use, antibiotic prescription rate (%): G1: 59/275 (21.5 %) G2: 101/275 (36.8 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: $p = 0.0005$	NR	Hospitalization, n (%): [mean (SD), median (range/IQR)] G1: 0 (0.0 %) G2: 1/275 (0.4 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2:	NR

Evidence Table 3C. Morbidity Outcomes for Burkhardt et al., 2010.³

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
NR	NR	NR	NR	NR

Evidence Table 4C. Mortality Outcomes for Burkhardt et al., 2010.³

In-hospital mortality	28-day mortality	Death	Pneumonia-related death	Proportion surviving hospitalization
NR	NR	NR	NR	NR

Evidence Table 5C. Function and Quality of Life Outcomes for Burkhardt et al., 2010.³

Days \leq 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score
Modified intention to treat analysis Days: [mean (SD), median (range/IQR)] G1: 9.04 G2: 9.00	NR	NR	NR

[test, result (p-value, 95% CI)] G1/G2: difference between G1 and G2 0.04 days, 95% CI -0.53 to 0.95) Worst case sensitivity analysis Days: [mean (SD), median (range/IQR)] G1: 9.06 G2: 8.80 [test, result (p-value, 95% CI)] G1/G2: difference between G1 and G2 0.25 days, 95% CI -0.52 to 1.03)			
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Evidence Table 6C. Adverse Effects and Adherence for Burkhardt et al., 2010.³

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence
NR	Antibiotic adverse effects (%): G1: 11 G2: 16 [test, result (p-value, 95% CI)] G1/G2: p = 0.331	NR	NR

Evidence Table 7C. Randomized Trial Study Quality Ratings for Burkhardt et al., 2010.³

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results
Y balanced Y-concealment	Y	Y	Y	Y	Y	Y

Evidence Table 1D. Study Description Table for Christ-Crain et al., 2004.⁴

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Christ-Crain et al., 2004. Country, institution type: Switzerland, University Hospital Enrollment period: December 16, 2002, April 13, 2003 Funding: Brahms, Dept of Medicine, Freiwillige Akademische Gesellschaft Basel Author industry relationship disclosures: 1 author consultant, recipient of payments from Brahms	Design: Prospective, cluster-randomized, single-blinded study Interventions: G1: Procalcitonin G2: Control Presenting condition: LRTI Setting: ED 4119 patients in ED 597 (14 %) with cough, dyspnea Screened Excluded N at enrollment: G1: 124 G2: 119 N at follow-up: G1: 112 (4 died, 8 LTFU) G2: 110 (4 died, 5 LTFU) Average follow-up, days: [mean (SD), median (range/IQR)] G1: G2:	Primary outcome: Use of antibiotics % prescription Patient-days RR antibiotic exposure for LRTI and AECOPD 95 % chance of detecting a 30 % reduction in antibiotic exposure Secondary outcomes: Clinical and laboratory outcome QOL Temp WBC count CRP PCT Admission rates LOS ICU Death for LRTIs Re-exacerbation, readmission for AECOPD Response criteria, independent outcome assessor: Assay type: Kryptor PCT, Brahms Decision-making: G1: For antibiotic initiation PCT < 0.1, antibiotics strongly discouraged	Inclusion criteria: <ul style="list-style-type: none"> Cough Dyspnea Both Lower RTI Exclusion criteria: <ul style="list-style-type: none"> Severely immunocompromised Neutropenic SCT Cystic fibrosis TB Nosocomial pneumonia HIV with CD4 < 200/mm³ 	Age, years: mean (SD): G1: 62.8 (19.8) G2: 65.3 (17.3) [test, result (p-value, 95% CI)] G1/G2: NSS Men, n (%): G1: 67 (54 %) G2: 61 (51 %) [test, result (p-value, 95% CI)] G1/G2: NSS Current smoker, n, (%): G1: 27 (22 %) G2: 35 (29 %) [test, result (p-value, 95% CI)] G1/G2: NSS Pack- years: mean (SD): G1: 41.4 (25.0) G2: 40.0 (26.0) [test, result (p-value, 95% CI)] G1/G2: NSS G1/G2: NSS Abnormal CXR, n, (%): G1: 48 (39 %) G2: 46 (39 %) [test, result (p-value, 95% CI)] G1/G2: NSS CAP, n, (%): G1: 42 (34 %) G2: 45 (38 %)	Coronary artery disease, n (%): [test, result (p-value, 95% CI)] G1: 27 (22 %) G2: 32 (27 %) G1/G2: NSS Congestive heart failure, n (%): G1: 11 (9%) G2: 7 (6 %) [test, result (p-value, 95% CI)] G1/G2: NSS Peripheral vascular disease, n (%): G1: 10 (8 %) G2: 9 (8 %) [test, result (p-value, 95% CI)] G1/G2: NSS Cerebrovascular disease, n (%): G1: 4 (3 %) G2: 5 (4.5) [test, result (p-value, 95% CI)] G1/G2: NSS Renal dysfunction, n (%): 22 (18 %) G1: 18 (15 %) G2: [test, result (p-value, 95% CI)]

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
		<p>PCT 0.1-0.25. antibiotics discouraged PCT 0.25-0.5, antibiotics encouraged PCT 0.5 or greater, antibiotics strongly encouraged</p> <p>G2: Standard therapy</p> <p>Decision-making: G1: For antibiotic discontinuation PCT < 0.25, d/c antibiotics</p> <p>G2: Standard therapy</p> <p>Condition = definition:</p>		<p>[test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>AECOPD, n, (%): G1: 29 (23 %) G2: 31 (26 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Acute bronchitis, n, (%): G1: 28 (23 %) G2: 31 (26 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Asthma attack, n, (%): G1: 10 (8 %) G2: 3 (3 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Other, n, (%): G1: 15 (12 %) G2: 9 (8 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>PCT: mean (SD): G1: 1.6 (7.7) G2: 1.6 (4.2) [test, result (p-value, 95% CI)] G1/G2: NSS</p>	<p>G1/G2: NSS</p> <p>Liver dysfunction, n (%): 6 (5 %) G1: 6 (5 %) G2: [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Diabetes mellitus, n (%): G1: 15 (12 %) G2: 17 (14 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Initial VAS: [mean (SD), median (range/IQR)] G1: 42.5 (20.4) G2: 43.1 (21.0) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Initial Quality of life: [mean (SD), median (range/IQR)] G1: 41.3 (14.3) G2: 39.3 (13.2) [test, result (p-value, 95% CI)] G1/G2: NSS</p>

Evidence Table 2 D. Intermediate Outcomes for Christ-Crain et al., 2004.⁴

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
<p>Days: [mean (SD), median (range/IQR)] G1: 10.9 +/- 3.6 G2: 12.8 +/- 5.5 [<i>test, result (p-value, 95% CI)</i>] G1/G2: p =0.03</p> <p>Incidence density antibiotic exposure: (rate days exposed per 1,000 patient-days) G1: 332 +/- 433 G2: 661 +/- 398 [<i>test, result (p-value, 95% CI)</i>] G1/G2: p < 0.0001</p> <p>Antibiotic cost per patient, US \$, mean(SD): G1: 96.3 (172.8) G2: 202.5 (250.6) [<i>test, result (p-value, 95% CI)</i>] G1/G2: p < 0.0001</p>	<p>Any antibiotic use, antibiotic prescription rate (%): G1: 55/124 (44 %) G2: 99/119 (83 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: p < 0.001</p> <p>G1-CAP: 38/42 G1-AECOPD: 11/29 G1-Bronchitis: 4/28 G1-Asthma: 0/10 G1-Others: 2/15 G2-CAP: 45/45, p = 0.003 G2-AECOPD: 27/31, p < 0.001 G2-Bronchitis: 16/31, p = 0.003 G2-Asthma: 2/3, p = 0.003 G2-Others: 9/9, p < 0.001 [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p>	NR	<p>Admission rate (%): G1: 101 (81 %) G2: 88 (74 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p> <p>Days: [mean (SD), median (range/IQR)] G1: 10.7 (8.9) G2: 11.2 (10.6) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p>	<p>ICU admission (%): G1: 5 (4 %) G2: 6 (5 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p>

Evidence Table 3D. Morbidity Outcomes for Christ-Crain et al., 2004.⁴

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
NR	NR	NR	NR	NR

Evidence Table 4D. Mortality Outcomes for Christ-Crain et al., 2004.⁴

In-hospital mortality	28-day mortality	Death	Pneumonia-related death	Proportion surviving hospitalization
NR	NR	<p>Proportion (%): G1: 4 (3 %) G2: 4 (3 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p>	NR	NR

Evidence Table 5D. Function and Quality of Life Outcomes for Christ-Crain et al., 2004.⁴

Days ≤ 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score
NR	NR	Final VAS: [mean (SD), median (range/IQR)] G1: 65.1 (21.8) G2: 64.1 (21.5) [test, result (p-value, 95% CI)] G1/G2: NSS	Final Quality of life: [mean (SD), median (range/IQR)] G1: 21.9 (14.7) G2: 22.9 (15.1) [test, result (p-value, 95% CI)] G1/G2: NSS

Evidence Table 6D. Adverse Effects and Adherence for Christ-Crain et al., 2004.⁴

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence
NR	NR	NR	NR

Evidence Table 7D. Randomized Trial Study Quality Ratings for Christ-Crain et al., 2004.⁴

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results
Y-balanced N/A-concealment	Y	Y	Y	Y	Y	N

Evidence Table 1E. Study Description Table for Christ-Crain et al., 2006.⁵

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Christ-Crain et al., 2006. Country, institution type: Switzerland, University Hospital of Basel Enrollment period: November 2003–February 2005 Funding: Brahms, Pfizer, Mepha, University Hospital of Basel Author industry relationship disclosures: 1 author received grants and lecture fees from Brahms, 1 author was on the Brahms advisory board for lecture fees	Design: RCT, 1:1, intent-to-treat Interventions: G1: G2: Presenting condition: CAP admitted to ED, single center Setting: ED 404 with CAP 102 excluded 37 immuno-compromised 3 TB 1 cystic fibrosis 17 HAP 17 no infiltrate 2 death before inclusion 25 no consent N at enrollment: G1: 151 G2: 151 N at follow-up: G1: 131 (20 died) G2: 131 (18 died, 2 LTFU) Average follow-up, days: [mean (SD), median (range/IQR)] G1: G2:	Primary outcome: Total antibiotic use (prescription) and duration Secondary outcomes: Laboratory, clinical outcomes Also cost assessment, direct (PCT, antibiotics) Indirect (adverse events, multidrug resistance, etc.) not considered Response criteria, independent outcome assessor: Assay type: Kryptor PCT, Brahms Decision-making: G1: 2 interventions For antibiotic initiation and discontinuation PCT < 0.1 antibiotics strongly discouraged	Inclusion criteria: <ul style="list-style-type: none"> • > 18 years of age • CAP principle diagnosis defined by new infiltrate on CXR and one of the following: cough, sputum production, dyspnea, fever > 38° C, abnormal breath sounds, white blood count > 10,000 or < 4,000 Exclusion criteria: <ul style="list-style-type: none"> • Cystic fibrosis • TB • HAP • severely immuno-compromised hosts 	Age, years: mean (SD) G1: 70 (17) G2: 70 (17) [test, result (p-value, 95% CI)] G1/G2: NSS Men, n (%): G1: 94 (62 %) G2: 93 (62%) [test, result (p-value, 95% CI)] G1/G2: NSS Current smoker, n (%): G1: 34 (23 %) G2: 39 (26 %) [test, result (p-value, 95% CI)] G1/G2: NSS Pack- years: mean (SD) G1: 42 (27) G2: 38 (20) [test, result (p-value, 95% CI)] G1/G2: NSS Fever: [mean (SD)] G1: 38.4 (1.1) G2: 38.4 (1.1) [test, result (p-value, 95% CI)] G1/G2: NSS PCT: median (range) G1: 0.57 (0.2-2.5) G2: 0.44 (0.2-1.9)	Coronary artery diseases, n (%):] G1: 49 (33 %) G2: 48 (32 %) G1/G2: NSS Hypertensive heart failure, n (%): G1: 42 (28 %) G2: 36 (24 %) [test, result (p-value, 95% CI)] G1/G2: NSS Congestive heart failure, n (%): G1: 7 (5 %) G2: 9 (6 %) [test, result (p-value, 95% CI)] G1/G2: NSS Peripheral vascular disease, n (%): G1: 11 (7 %) G2: 9 (6 %) [test, result (p-value, 95% CI)] G1/G2: NSS Cerebrovascular disease, n (%): G1: 8 (5 %) G2: 8 (5 %) [test, result (p-value, 95% CI)] G1/G2: NSS

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
	6 weeks	<p>PCT ≥ 0.1, < 0.25, antibiotics discouraged</p> <p>PCT ≥ 0.25, ≤ 0.5, antibiotics encouraged</p> <p>PCT > 0.5, antibiotics strongly encouraged</p> <p>If baseline > 10, antibiotics discontinued if less than 10 % of initial value</p> <p>G2: Standard therapy</p>		<p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>CRP: median (range)</p> <p>G1: 111 (57-204)</p> <p>G2: 152 (72-212)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>WBC count: [mean (SD)]</p> <p>G1: 13.7 (6.7)</p> <p>G2: 13.4 (6.6)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>QOL score: mean (SD)</p> <p>G1: 40 (13)</p> <p>G2: 39 (13)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>VAS, %: mean (SD)</p> <p>G1: 43 (20)</p> <p>G2: 39 (21)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>PSI points: mean (SD)</p> <p>G1: 99.7 (36.1)</p> <p>G2: 99.2 (34.5)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p>	<p>Renal dysfunction, n (%):</p> <p>G1: 36 (24 %)</p> <p>G2: 45 (30 %)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2:</p> <p>Liver disease, n (%):</p> <p>G1: 12 (8 %)</p> <p>G2: 19 (13 %)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>Diabetes mellitus, n (%):</p> <p>G1: 32 (21 %)</p> <p>G2: 29 (19 %)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>COPD, n (%):</p> <p>G1: 44 (29 %)</p> <p>G2: 32 (21 %)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>Cancer, n (%):</p> <p>G1: 25 (17 %)</p> <p>G2: 23 (15 %)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p>

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
				<p>PSI class I, II, III, n (%): G1: 54 (36 %) G2: 66 (44 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p> <p>PSI class IV, n (%): G1: 68 (45 %) G2: 62 (41 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p> <p>PSI class V, n (%): G1: 29 (19 %) G2: 23 (15 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p>	

Evidence Table 2 E. Intermediate Outcomes for Christ-Crain et al., 2006.⁵

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
<p>Days: [mean (SD), median (range/IQR)] G1: 5.8 (5.3) G2: 12.9 (6.5) [<i>test, result (p-value, 95% CI)</i>] G1/G2: p < 0.001</p> <p>Days, if prescribed: [mean (SD), median (range/IQR)] G1: 6.8 (5.1) G2: 13.1 (6.4) [<i>test, result (p-value, 95% CI)</i>] G1/G2: p < 0.001</p> <p>Days if bacteremic: [mean (SD), median (range/IQR)] G1: 13.0 (8.9) G2: 13.9 (4.9) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p> <p>Incidence density antibiotic exposure: (rate days exposed per 1,000 patient-days) G1: 136 (95% CI 126 to 146) G2: 323 (95% CI 309 to 338) [<i>test, result (p-value, 95% CI)</i>] G1/G2: p < 0.001</p> <p>Antibiotic cost, US \$: G1: 29,248 G2: 59,535 [<i>test, result (p-value, 95% CI)</i>] G1/G2: p < 0.001</p> <p>Antibiotic cost per patient, US \$: G1: 100 (33-186) G2: 190 (133-337) [<i>test, result (p-value, 95% CI)</i>] G1/G2: p < 0.001</p>	<p>Any antibiotic use, antibiotic prescription rate (%): G1: 128 (85 %) G2: 149 (99 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: p < 0.001</p>	NR	<p>Hospitalization (%): G1: 146 (97 %) G2: 146 (97 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p> <p>Days: [mean (SD), median (range/IQR)] G1: 12.0 (9.1) G2: 13.0 (9.0) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p>	<p>ICU admission (%): G1: 20 (13 %) G2: 21 (14 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p>

Evidence Table 3E. Morbidity Outcomes for Christ-Crain et al., 2006.⁵

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
NR	NR	<p>Microbiological recurrence of infection (%): G1: 1 (1 %) G2: 0 [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Clinical/radiological recurrence (%): G1: 4 (3 %) G2: 4 (3 %) [test, result (p-value, 95% CI)] G1/G2:</p> <p>Persistent of pneumonia: G1: 1 (1 %) G2: 3 (2 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Empyema, n (%): G1: 4 (3 %) G2: 7 (5 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>ARDS, n (%): G1: 1 (1 %) G2: 1 (1 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p>	NR	<p>Success at follow-up, n, (%): G1: 127/151 (84 %) G2: 124/151 (82 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Clinical cure, n, (%): G1: 108/127 (85 %) G2: 105/124 (85 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Improved, n, (%): G1: 19/127 (15 %) G2: 19/124 (15 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p>

Evidence Table 4E. Mortality Outcomes for Christ-Crain et al., 2006.⁵

In-hospital mortality	28-day mortality	Death	Pneumonia-related death	Proportion surviving hospitalization
NR	NR	Proportion (%): G1: 18 (12 %) G2: 20 (13 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS	Proportion (%): G1: 10 (56 %) G2: 10 (50 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS	NR

Evidence Table 5E. Function and Quality of Life Outcomes for Christ-Crain et al., 2006.⁵

Days ≤ 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score
NR	NR	Function: [mean (SD), median (range/IQR)] G1: 79 (18) G2: 74 (20) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS	Quality of life: [mean (SD)] G1: 10 (10) G2: 11 (10) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS

Evidence Table 6E. Adverse Effects and Adherence for Christ-Crain et al., 2006.⁵

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence
NR	NR	NR	NR

Evidence Table 7E. Randomized Trial Study Quality Ratings for Christ-Crain et al., 2006.⁵

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results
Y- balanced Y-concealment	Y	Y	Y	Y	Y	Y

Evidence Table 1F. Study Description Table for Chromik et al., 2005.⁶

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Chromik et al., 2005.	Design: RCT, 1:1, single arm with respect to PCT	Primary outcome: Post-op complications; local wound or systemic infection Secondary outcomes: Mortality for post-op infections, complications, fever, WBC, duration of antibiotics, LOS No power calculation	Inclusion criteria: <ul style="list-style-type: none"> • Elective colonic surgery • Written consent • Peri-operative antibiotic prophylaxis for < 24 hours • PCT < 1.0 pre-op • PCT > 1.5 post-op • Age > 18 years Exclusion criteria: <ul style="list-style-type: none"> • > 24 hours of peri-operative antibiotic prophylaxis • SZ • pregnancy or lactation • cephalosporin allergy • renal failure • HIV • immune deficiency • investigational treatment within last 30 days • current cytostatic immunosuppressive medications 	Age, years: [mean (SD), median (range/IQR)] G1: 62 (38-82) G2: 70 (62-89) [test, result (p-value, 95% CI)] G1/G2:	NR

Evidence Table 2 F. Intermediate Outcomes for Chromik et al., 2005.⁶

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
Days: median (range): G1: 5.5 (4-20) G2: 9 (3-16) [test, result (p-value, 95% CI)] G1/G2: NSS	NR	NR	Days: median (range): G1: 18 (10-49) G2: 30 (9-82) [test, result (p-value, 95% CI)] G1/G2: NSS	NR

Evidence Table 3F. Morbidity Outcomes for Chromik et al., 2005.⁶

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
NR	Wound infection (%): G1: 1/10 G2: 2/10 [test, result (p-value, 95% CI)] G1/G2: G1 + G2: 3/20 (15 %) G3: 16/230 (7.0 %) No antibiotics or further surgery Systemic infection (%): G1: 3/10 G2: 8/10 [test, result (p-value, 95% CI)] G1/G2: p = 0.001 G1 + G2: 11/20 (55 %) G3: 4/230 (1.7 %) No antibiotics or further surgery NPV for wound 93 % 98.3 % for systemic infection Multiple systemic infections (%): G1: 0/3 G2: 1/7 [test, result (p-value, 95% CI)] G1/G2:	NR	SIRS (C1), sepsis (C2), severe sepsis (C3), septic shock (C4), (%) G1-C1 1 G1-C2 0 G1-C3 1 G1-C4 0 G2-C1 1 G2-C2 4 G2-C3 2 G2-C4 1 Total G1: 2 Total G2: 8 [test, result (p-value, 95% CI)] G1/G2: p = 0.007 for total Requiring pressors (%): G1: 1 G2: 6 [test, result (p-value, 95% CI)] G1/G2: p = 0.019	NR

Evidence Table 4F. Mortality Outcomes for Chromik et al., 2005.⁶

In-hospital mortality	28-day mortality	Death	Pneumonia-related death	Proportion surviving hospitalization
Proportion (%): G1: 1/10 (10 %) G2: 3/10 (30 %) [test, result (p-value, 95% CI)] G1/G2:	NR	NR	NR	NR

Evidence Table 5F. Function and Quality of Life Outcomes for Chromik et al., 2005.⁶

Days ≤ 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score
NR	NR	NR	NR

Evidence Table 6F. Adverse Effects and Adherence for Chromik et al., 2005.⁶

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence
NR	NR	NR	NR

Evidence Table 7F. Randomized Trial Study Quality Ratings for Chromik et al., 2005.⁶

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results
Y	Y	Y	Y	Y	Y	Y

Evidence Table 1G. Study Description Table for Hochreiter et al., 2009.⁷

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Hochreiter et al., 2009. Country, institution type: Germany, University affiliate Enrollment period: January 2006-March 2007 Funding: Not listed Author industry relationship disclosures: 1 author speaker's bureau, no other conflicts	Design: RCT, 1:1 randomization Interventions: G1: PCT-guided antibiotics therapy G2: Standard therapy Presenting condition: Proven or suspected post-op bacterial infection Setting: ICU N at enrollment: G1: 57 G2: 53 N at follow-up: G1: 57 G2: 53 Average follow-up, days: [mean (SD), median (range/IQR)] G1: G2:	Primary outcome: Response criteria, independent outcome assessor: No outcomes specified, no power calculation Assay type: Kryptor, Brahms Also CRP, IL-6, WBC Decision-making: G1: PCT Algorithm PCT < 1.0 and clinical signs resolved, stop antibiotics; PCT > 1.0 but dropped to 25-35 % of initial value over 3 days; stop antibiotics G2: Antibiotics standard regimen for 8 days Condition = definition:	Inclusion criteria: <ul style="list-style-type: none"> Proven or suspected bacterial infections needing antibiotics + 2 SIRS criteria Exclusion criteria: <ul style="list-style-type: none"> Refused consent Antibiotics initiated before ICU admission 	Age, years: Mean (SD) G1: 67.3 (14.4) G2: 66.6 (15.5) [test, result (p-value, 95% CI)] G1/G2: NSS Disease, n, (%): Pneumonia G1: 24/57 G2: 19/53 [test, result (p-value, 95% CI)] G1/G2: NSS Pneumonia G1: 24/57 G2: 19/53 [test, result (p-value, 95% CI)] G1/G2: NSS Peritonitis G1: 29/57 G2: 30/53 [test, result (p-value, 95% CI)] G1/G2: NSS Skin, soft tissue infection G1: 2/57 G2: 1/53 [test, result (p-value, 95% CI)] G1/G2: NSS	SAPS II, Mean (SD): [test, result (p-value, 95% CI)] G1: 40.1 ± 17.1 G2: 40.5 ± 15.1 G1/G2: NSS

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
				UTI G1: 2/57 G2: 3/53 [test, result (p-value, 95% CI)] G1/G2: NSS	

Evidence Table 2 G. Intermediate Outcomes for Hochreiter et al., 2009.⁷

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
Days: [mean (SD), median (range/IQR)] G1: 5.9 (1.7) G2: 7.9 (0.5) [test, result (p-value, 95% CI)] G1/G2: p < 0.001	NR	No differences in antibiotics used	NR	ICU LOS, days, Mean (SD): G1: 15.5 (12.5) G2: 17.7 (10.1) [test, result (p-value, 95% CI)] G1/G2: p = 0.046

Evidence Table 3G. Morbidity Outcomes for Hochreiter et al., 2009.⁷

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
NR	NR	NR	NR	NR

Evidence Table 4G. Mortality Outcomes for Hochreiter et al., 2009.⁷

In-hospital mortality	28-day mortality	Death	Pneumonia-related death	Proportion surviving hospitalization
NR	NR	Proportion, (%): G1: 15/57 G2: 14/53 [test, result (p-value, 95% CI)] G1/G2: NSS	NR	NR

Evidence Table 5G. Function and Quality of Life Outcomes for Hochreiter et al., 2009.⁷

Days ≤ 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score
NR	NR	NR	NR

Evidence Table 6G. Adverse Effects and Adherence for Hochreiter et al., 2009.

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence
NR	NR	NR	NR

Evidence Table 7G. Randomized Trial Study Quality Ratings for Hochreiter et al., 2009.⁷

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results
Y*	Y	Y	Y	Y	Y	Y

*No details on allocation concealment but groups were comparable

Evidence Table 1H. Study Description Table for Jensen et al., 2011.⁸

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Jensen et al., 2011. Country, institution type: Denmark, Tertiary Care Public University Hospital Enrollment period: 2006-2009 Funding: Danish State, Lundbeck Foundation, Toyota Foundation, H.P. Moller Foundation, Hurbec Foundation, and Capitol Region of Denmark Author industry relationship disclosures: One author disclosed speaking and travel reimbursement from Brahms	Design: RCT; Open label Interventions: G1: expanded diagnostic radiology and expanded spectrum of antibiotic therapy for “alert procalcitonin”; de-escalation only after PCT < 1.0 for 3 days G2: Standard microbiologic sampling, radiology, and antibiotic therapy Presenting condition: Critically ill in ICU Setting: ICUs N at enrollment: G1: 604 G2: 596 N at follow-up: G1: 604 G2: 596 Average follow-up, days: [mean (SD), median (range/IQR)] G1: 28 days G2: 28 days	Primary outcome: 28 day mortality Secondary outcomes: Shorter ICU LOS; shorter duration of organ failure Response criteria, independent outcome assessor: Investigators, treating physicians, and coordinator were unaware of outcomes as well as procalcitonin measurements in the control group Assay type: Brahms Kryptor-PCT Decision-making: G1: Intervention algorithm based on “alert procalcitonin” ($\geq 1.0 \text{ ng/mL}$ that was not decreasing by at least 10 % from the previous day). At baseline a single measurement of $> 1.0 \text{ ng/ml}$ was also considered alert procalcitonin; G2: Standard of care algorithm	Inclusion criteria: <ul style="list-style-type: none"> • ≥ 18 years of age • Enrolled within 24 hours of admission to ICU • Expected ICU stay ≥ 24 hours Exclusion criteria: <ul style="list-style-type: none"> • High bilirubin ($> 40 \text{ mg/dL}$) or • High triglycerides ($> 1,000 \text{ mg/dL}$) • Patients judged to be at an increased risk from blood sampling 	Age, years: median (range/IQR) G1: 67 (58-76) G2: 67 (58-75) G1/G2: Women, n (%): G1: 274 (45.4 %) G2: 263 (44.1 %) G1/G2: NSS APACHE Score: median (range/IQR) G1: 18 (13-25) G2: 18 (13-24) G1/G2: NSS Infection, Clinical Assessment No infection, n, (%): G1: 86 (14.2 %) G2: 118 (19.8 %) G1/G2: NSS Infection, n, (%): G1: 271 (44.9 %) G2: 266 (44.6 %) G1/G2: NSS Severe sepsis, septic shock, n, (%): G1: 247 (40.9 %)	Surgical patient, n (%): [<i>test, result (p-value, 95% CI)</i>] G1: 227 (37.6 %) G2: 260 (43.6 %) G1/G2: NSS 1 chronic co-morbidity, n (%): G1: 257 (42.6 %) G2: 279 (46.8 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS 2 chronic co-morbidities, n (%): G1: 171 (28.3 %) G2: 173 (29.0 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS 3 chronic co-morbidities, n (%) Congestive heart failure, n (%): G1: 53 (8.8 %) G2: 42 (7.1 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS

				G2: 212 (35.6 %) G1/G2: NSS	
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Evidence Table 2 H. Intermediate Outcomes for Jensen et al., 2011.⁸

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
<p>Days: median (range/IQR) G1: 6 (3-11) G2: 4 (3-10) [test, result (p-value, 95% CI)] G1/G2:</p> <p>Days spent in ICU with ≥ 3 antibiotics, n (%): G1: 3570 (65.5 %) G2: 2721 (57.7 %) G1/G2: 7.8, p = 0.002</p>	NR	NR	NR	<p>Days: median (range/IQR) G1: 6 (3-12) G2: 5 (3-11) [test, result (p-value, 95% CI)] G1/G2: p = 0.004</p>

Evidence Table 3H. Morbidity Outcomes Jensen et al., 2011.⁸

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
NR	<p>ICU days on mechanical ventilation: [mean (SD), median (range/IQR)] G1: 3569 (65.5 %) G2: 2861 (60.7 %) [test, result (p-value, 95% CI)] G1/G2: 4.9 (3.0 to 6.7)</p> <p>ICU days with GFR < 60 mL/1.73 ml) on mechanical ventilation: [mean (SD), median (range/IQR)] G1: 2796 (51.3 %) G2: 2187 (46.4 %) [test, result (p-value, 95% CI)] G1/G2: 5.0 (3.0 to 6.9)</p>	NR	NR	NR

Evidence Table 4H. Mortality Outcomes for Jensen et al., 2011.⁸

In-hospital mortality	28-day mortality	Death	Pneumonia-related death	Proportion surviving hospitalization
NR	<p>Proportion (%): G1: 190/604 (31.5 %) G2: 191 /596 (32.0 %) [test, result (p-value, 95% CI)] G1/G2: -0.6 % (-4.7 to 5.9 %)</p>	NR	NR	NR

Evidence Table 5A Function and Quality of Life Outcomes for Jensen et al., 2011.⁸

Days ≤ 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score
NR	NR	NR	NR

Evidence Table 6H. Adverse Effects and Adherence for Jensen et al., 2011.⁸

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence	
NR	NR	NR	<p>Proportion of patients with baseline PCT alert who received antibiotics (G1) (%): G1: 256/312 (82.1 %)</p> <p>Proportion of patients at baseline who were judged to have severe sepsis or septic shock and who received antibiotics (G2) G2: 172/209 (82.4 %)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2:</p>	NR

Evidence Table 7H. Randomized Trial Study Quality Ratings for Jensen et al., 2011.⁸

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results
Y	Y	Y	Y	Y	Y	Y

Evidence Table 11. Study Description Table for Kristoffersen et al., 2009.⁹

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Kristoffersen et al., 2009. Country, institution type: Denmark Enrollment period: June 1, 2006 to April 30, 2007 Funding: Danish Medical Research Council, Danish Lung Association Author industry relationship disclosures: No conflicts	Design: RCT, multi-center Interventions: G1: G2: Presenting condition: Hospitalized patients with LRTI, suspicion of pneumonia based on history (cough, sputum, dyspnea, and fever > 38o C) and physical (no CXR requirement) Setting: 223 enrolled 210 analyzed N at enrollment: G1: 103 G2: 107 N at follow-up: G1: 103 G2: 107 Average follow-up, days: [mean (SD), median (range/IQR)] G1: G2:	Primary outcome: Primary-intent to treat analysis Antibiotics use (days of antibiotics during hospitalization) LOS hospital Secondary outcome: Proportion of patients for whom physicians disregarded treatment guidelines 90 % power to detect a 20 % decrease in antibiotic exposure Response criteria, independent outcome assessor: Assay type: Kryptor, Brahms Decision-making: G1: PCT guided continuation or cessation of antibiotics If PCT < 0.25 ng/mL, antibiotics should be discouraged PCT 0.25-5.0, antibiotic encouraged PCT > 0.5, antibiotic strongly encouraged	Inclusion criteria: <ul style="list-style-type: none"> ≥ 18 years of age Suspected pneumonia One or more symptoms of cough, expectoration, dyspnea, fever > 38° C Exclusion criteria: <ul style="list-style-type: none"> 	Age, years: [mean (SD), median (range/IQR)] G1: 67.2 (17.6) G2: 67 (15.6) [test, result (p-value, 95% CI)] G1/G2: NSS Men, n (%): G1: 54 (52 %) G2: 58 (54 %) [test, result (p-value, 95% CI)] G1/G2: NSS Current/former smoker, n (%): G1: 68 (66 %) G2: 82 (77 %) [test, result (p-value, 95% CI)] G1/G2: NSS Antibiotics pre-treatment, n (%): G1: 48 (47 %) G2: 46 (43 %) [test, result (p-value, 95% CI)] G1/G2: NSS PSI, mean (SD): G1: 79.2 (27.8) G2: 75.8 (24.3) [test, result (p-value, 95% CI)] G1/G2: NSS	Diabetes mellitus, n (%): G1: 13 (13 %) G2: 11 (10 %) [test, result (p-value, 95% CI)] G1/G2: NSS Cancer, n (%): G1: 7 (7 %) G2: 0 [test, result (p-value, 95% CI)] G1/G2: Congestive heart failure, n (%): G1: 15 (15 %) G2: 14 (13 %) [test, result (p-value, 95% CI)] G1/G2: NSS Cerebrovascular disease, n (%): G1: 4 (4 %) G2: 4 (4 %) [test, result (p-value, 95% CI)] G1/G2: NSS COPD, n (%): G1: 38 (37 %) G2: 51 (48 %) [test, result (p-value, 95% CI)] G1/G2: NSS

		G2:		PSI, I-III, n (%): G1: 65 (63 %) G2: 78 (73%) [test, result (p-value, 95% CI)] G1/G2: NSS	Final Diagnosis CAP, n (%): G1: 47 (46 %) G2: 50 (47 %) [test, result (p-value, 95% CI)] G1/G2: NSS
				PSI, IV, n (%): G1: 35 (34 %) G2: 27 (25 %) [test, result (p-value, 95% CI)] G1/G2: NSS	AECOPD, n (%): G1: 28 (37 %) G2: 32 (30 %) [test, result (p-value, 95% CI)] G1/G2: NSS
				PSI, V, n (%): G1: 3 (3 %) G2: 2 (2 %) [test, result (p-value, 95% CI)] G1/G2: NSS	Acute bronchitis, n (%): G1: 3 (3 %) G2: 5 (5 %) [test, result (p-value, 95% CI)] G1/G2: NSS
				Abnormal CXR, n (%): G1: 40 (39 %) G2: 43 (40 %) [test, result (p-value, 95% CI)] G1/G2: NSS	Acute asthma, n (%): G1: 2 (2 %) G2: 3 (3 %) [test, result (p-value, 95% CI)] G1/G2: NSS
				WBC, mean (SD): G1: 13.2 (7.5) G2: 12.1 (5.9) [test, result (p-value, 95% CI)] G1/G2: NSS	Viral infection, n (%): G1: 2 (2 %) G2: 2 (2 %) [test, result (p-value, 95% CI)] G1/G2: NSS
				CRP, mean (SD): G1: 1091 (1080) G2: 971 (1000) [test, result (p-value, 95% CI)] G1/G2: NSS	Other, n (%): G1: 21 (20 %) G2: 15 (14 %) [test, result (p-value, 95% CI)] G1/G2: NSS
				PCT, median (range): G1: 0.14 (0.05-42.13) G2: 0.13 (0.02-30.12) [test, result (p-value, 95% CI)]	

			G1/G2: NSS	
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Evidence Table 2 I. Intermediate Outcomes for Kristoffersen et al., 2009.⁹

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
<p>Days: [mean (SD), median (range/IQR)] G1: 5.1 (95 % CI 4.4-6.0) G2: 6.8 (95 % CI 5.9-7.7) [<i>test, result (p-value, 95% CI)</i>] G1/G2: <i>p</i> = 0.007 In 42/103 patients (41 %), treatment guidelines were ignored 47 % due to clinical presentation, 41 % due to late report 1.6 days to get report</p>	<p>Any antibiotic use, antibiotic prescription rate (%): G1: 88 (85 %) G2: 85 (79 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p>	NR	<p>Days: [mean (SD), median (range/IQR)] G1: 5.9 (95 % CI 5.1-6.9) G2: 6.7 (95 % CI 5.9-7.7) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p>	ICU admission (%): G1: 7 (7 %) G2: 5 (5 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS

Evidence Table 3I. Morbidity Outcomes for Kristoffersen et al., 2009.⁹

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
NR	NR	NR	NR	NR

Evidence Table 4I. Mortality Outcomes for Kristoffersen et al., 2009.⁹

In-hospital mortality	28-day mortality	Death	Pneumonia-related death	Proportion surviving hospitalization
<p>Proportion (%): G1: 2 (2 %) G2: 1 (1 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p>	<p>Proportion (%): G1: G2: [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p>	<p>Proportion (%): G1: G2: [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p>	<p>Proportion (%): G1: G2: [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p>	<p>Proportion (%): G1: G2: [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p>

Evidence Table 5I. Function and Quality of Life Outcomes for Kristoffersen et al., 2009.⁹

Days ≤ 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score
NR	NR	NR	NR

Evidence Table 6I. Adverse Effects and Adherence for Kristoffersen et al., 2009.⁹

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence
NR	NR	NR	NR

Evidence Table 7I. Randomized Trial Study Quality Ratings for Kristoffersen et al., 2009.⁹

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results
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Y-balanced Y-concealment	Y	Y	Y	Y	Y	N
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Evidence Table 1J. Study Description Table for Long et al., 2011.¹⁰

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Long et al., 2011. Country, institution type: Shanghai China, University hospital Enrollment period: February 2005 – December 2008 Funding: Grant Shanghai Fifth People's Hospital Science Foundation Author industry relationship disclosures: Not stated	Design: RCT, intention to treat Interventions: G1: PCT-guided antibiotic therapy G2: standard antimicrobial therapy Presenting condition: Suspected CAP outpatient Setting: ER 287 screened 172 enrolled N at enrollment: G1: 86 G2: 86 N at follow-up: G1: 77 4 lost to follow-up 4 withdrew 1 lung CA G2: 79 2 lost to follow-up 3 withdrew 2 TB Average follow-up,	Primary outcome: Total antibiotic use and duration of antibiotic treatment, antibiotic prescription rate Secondary outcomes: Treatment failure, treatment success, death, recurrence, relapse, patients lost to follow-up Response criteria, independent outcome assessor: Assay type: Kryptor-Brahms Decision-making: G1: PCT< 0.1 µg/L strongly discourage antibiotic use PCT 0.1-0.25 µg/L antibiotics discouraged PCT >0.25 antibiotics encouraged	Inclusion criteria: <ul style="list-style-type: none"> > 18 years of age PSI class I-III Exclusion criteria: <ul style="list-style-type: none"> Age 65 or older pregnancy Antibiotic 48-hour before enrollment systemic immune deficiency Withholding life-support Active TB 	Age, years: [mean (SD), median (range/IQR)] G1: 44 +/- 16 G2: 47 +/- 19 Males, n (%): G1: 46 (59.7) G2: 49 (62.0) Former Smokers, n (%): G1: 41 (53.2) G2: 45 (56.9)	Current Smokers, n (%): [test, result (p-value, 95% CI)] G1: 34 (44.2) G2: 33 (41.8) G1/G2: PSI class I-III n (%): I G1: 22 (28.6) I G2: 24 (30.4) II G1: 38 (49.3) II G2: 39 (49.4) III G1: 17 (22.1) III G2: 16 (20.2) Body temperature n : [mean (SD), median (range/IQR)]: G1: 38.6 +/- 1.3 G2: 38.4 +/- 1.2 PCT n : [mean (SD), median (range/IQR)]: [test, result (p-value, 95% CI)] G1/G2:

	days: 28 day follow-up	G2: Standard PCT levels tested at 6-12 hours then 3,6 and 8 days antibiotics were discontinued based on previous defined values			G1: 0.39 (0.26-1.12) G2: 0.42 (0.28-1.19) [test, result (p-value, 95% CI)]
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Evidence Table 2 J. Intermediate Outcomes for Long et al., 2011.¹⁰

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
Per protocol analysis median duration of therapy: Days: [mean (SD), median (range/IQR)] G1: 5 (3-6) G2: 7 (5-9) [test, result (p-value, 95% CI)] G1/G2: p<0.001	Antibiotic use on initial assessment, antibiotic prescription rate (%): G1: 84.4% G2: 97.5% [test, result (p-value, 95% CI)] G1/G2: p=0.0004 Total rate antibiotics exposure decreased in G1 RR 0.55 95% CI: 0.51-0.60 p=0.003	NR	NR	NR

Evidence Table 3J. Morbidity Outcomes for Long et al., 2011.¹⁰

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
All patient survived	NR	NR	NR	Clinical success (%): ITT analysis G1: 69 (85.2) G2: 72 (88.9) [test, result (p-value, 95% CI)] G1/G2: absolute difference -3.7 (14.1-6.7)

Evidence Table 4J. Mortality Outcomes for Long et al., 2011.¹⁰

In-hospital mortality	28-day mortality	Death	Pneumonia-related death	Proportion surviving hospitalization
NR	NR	NR	NR	NR

Evidence Table 5J. Function and Quality of Life Outcomes for Long et al., 2011.¹⁰

Days ≤ 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score
NR	NR	NR	NR

Evidence Table 6J. Adverse Effects and Adherence for Long et al., 2011.¹⁰

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence
NR	NR	NR	NR

Evidence Table 7J. Randomized Trial Study Quality Ratings for Long et al., 2011.¹⁰

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results
Y- balanced U-concealment	Y	Y	Y	Y	Y	N

Evidence Table 1K. Study Description Table for Manzano et al., 2010.¹¹

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Manzano et al., 2010. Country, institution type: Canada, CHU Ste-Justine, Montreal, Tertiary care center Enrollment period: Not given Funding: PCT-Q supplied by Brahms Author industry relationship disclosures: None disclosed	Design: RCT, 1:1 block randomization Interventions: G1: None; PCT result available, no recommendations G2: Blinded to PCT result Presenting condition: Fever Setting: Pediatric ED N at enrollment: G1: 220 G2: 220	Primary outcome: Antibiotic prescription rate 80 % power to detect a difference in rate of Antibiotic prescriptions Needed 335-419 Secondary outcomes: Hospitalization rate Additional studies, i.e., CXR, lumbar puncture; prescription rates without excluding patients treated for a bacterial infection	Inclusion criteria: <ul style="list-style-type: none"> Age 1-36 months T > 38° No identified source of infection Exclusion criteria: <ul style="list-style-type: none"> Congenital immune deficiencies Known bacterial infection ANC < 500 Children already treated with antibiotics 	Age, years: [mean (SD), median (range/IQR)] G1: 12 +/- 8 mos G2: 12 +/- 8 mos [test, result (p-value, 95% CI)] G1/G2: NSS Triage level (5), n (%): G1-1: 0 (0) G1-2: 26 (14) G1-3: 77 (40) G1-4: 88 (46) G1-5: 1 (1) G2-1: 0 (0) G2-2: 34 (18) G2-3: 74 (39) G2-4: 83 (43) G2-5: 1 (1) [test, result (p-value, 95% CI)] G1/G2: NSS Tmax: [mean (SD), median (range/IQR)] G1: 39.6 +/- 0.7	NR

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
	<p>N at follow-up: G1: 192 G2: 192</p> <p>Insufficient blood for 28 in each group</p>	<p>Response criteria, independent outcome assessor:</p> <p>Assay type: PCT-Q, Brahms</p> <p>Decision-making: G1: G2:</p>		<p>G2: 39.6 +/- 0.6 [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Fever duration, hours: [mean (SD), median (range/IQR)] G1: 62 +/- 48 G2: 64 +/- 50 [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>VAS for serious bacterial infection, %: median (range/IQR) G1: 19 (12-29) G2: 19 (11-31) [test, result (p-value, 95% CI)] G1/G2: NSS</p>	

Evidence Table 2 K. Intermediate Outcomes for Manzano et al., 2010.¹¹

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
NR	<p>All children</p> <p>Any antibiotic use, antibiotic prescription rate (%): G1: 48/192 (25) G2: 54/192 (28) [test, result (p-value, 95% CI)] G1/G2: -3 (-12 to 6)</p> <p>Children without SBI or neutropenia</p>	NR	<p>All children</p> <p>Hospitalization rate, n (%): G1: 50/192 (26) G2: 48/192 (25) [test, result (p-value, 95% CI)] G1/G2: 1 (-8 to 10)</p> <p>Children without SBI or neutropenia</p> <p>Hospitalization rate, n (%):</p>	NR

	<p>Any antibiotic use, antibiotic prescription rate (%): G1: 14/158 (9) G2: 16/154 (10) [test, result (p-value, 95% CI)] G1/G2: -2 (-8 to 5)</p>		<p>G1: 16/158 (10) G2: 11/154 (7) [test, result (p-value, 95% CI)] G1/G2: 3 (-3 to 10)</p>	
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Evidence Table 3K. Morbidity Outcomes for Manzano et al., 2010.¹¹

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
NR	NR	NR	NR	NR

Evidence Table 4K. Mortality Outcomes for Manzano et al., 2010.¹¹

In-hospital mortality	28-day mortality	Death	Pneumonia-related death	Proportion surviving hospitalization
NR	NR	NR	NR	NR

Evidence Table 5K. Function and Quality of Life Outcomes for Manzano et al., 2010.¹¹

Days ≤ 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score
NR	NR	NR	NR

Evidence Table 6K. Adverse Effects and Adherence for Manzano et al., 2010.¹¹

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence
NR	NR	NR	NR

Evidence Table 7K. Randomized Trial Study Quality Ratings for Manzano et al., 2010.¹¹

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results
Y	Y	Y	Y	Y	Y	N

Evidence Table 1L: Study Description Table for Nobre et al., 2008.¹²

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Nobre et al., 2008. Country, institution type: Switzerland, University Hospital, ICU Enrollment period: February 2006-April 2007 Funding: Not listed Author industry relationship disclosures: 2 authors with research funding from Brahms, and 1 author Brahms speaker's bureau	Design: RCT, 1:1 randomization Intent to treat Interventions: G1: PCT-guided antibiotics G2: Standard antibiotic therapy Presenting condition: Severe sepsis, septic shock Setting: ICU 282 assessed 203 excluded 42 > 48 hours antibiotics 35 severe immuno-suppression 37 long-term antibiotics anticipated 20 DNR 32 with consent issues 8 PSAR 7 endocarditis 6 early ICU discharge 16 other N at enrollment: G1: 39 G2: 40 N at follow-up: G1: 31	Primary outcome: Systemic antibiotic exposure 90 % power to detect a 33 % (4 day) difference in antibiotic duration Secondary outcomes: 28 day mortality, IH mortality, ICU LOS, cure, recurrence, superinfection Response criteria, independent outcome assessor: Assay type: Kryptor, Brahms Decision-making: G1: PCT-guided antibiotic discontinuation Baseline PCT > 1.0, PCT decreased by 90 % from peak or < 0.25, stop antibiotic Baseline PCT < 1.0, PCT < 0.1, discontinue antibiotics G2: Standard antibiotic therapy Condition = definition:	Inclusion criteria: <ul style="list-style-type: none"> Exclusion criteria: <ul style="list-style-type: none"> Pseudomonas aeruginosa, Acinetobacter, Listeria, Legionella, PCP, TB, other chronic infections Solid organ transplantation AIDS ANC < 500 Antibiotics > 48 hours before enrollment 	Age, years: [mean (SD), median (range/IQR)] G1: 64.0 (12.3) G2: 66.9 (13.8) [test, result (p-value, 95% CI)] G1/G2: NSS Male, n (%): G1: 21 (67.7 %) G2: 25 (67.6 %) [test, result (p-value, 95% CI)] G1/G2: NSS Disease Pneumonia, n, (%): G1: 22 (71.0 %) G2: 25 (67.6 %) [test, result (p-value, 95% CI)] G1/G2: NSS Abdominal sepsis, n, (%): G1: 2 (6.5 %) G2: 6 (16.2 %) [test, result (p-value, 95% CI)] G1/G2: NSS Urosepsis, n, (%): G1: 5 (16.1 %) G2: 5 (13.5 %) [test, result (p-value, 95% CI)] G1/G2: NSS	Cancer, n (%): [test, result (p-value, 95% CI)] G1: 4 (12.9 %) G2: 5 (13.9 %) G1/G2: NSS Immunosuppression, n (%): G1: 1 (3.2 %) G2: 1 (2.7 %) [test, result (p-value, 95% CI)] G1/G2: NSS Cardiomyopathy, n (%): G1: 11 (35.5 %) G2: 17 (45.5 %) [test, result (p-value, 95% CI)] G1/G2: COPD, n (%): G1: 12 (38.7 %) G2: 7 (18.9 %) [test, result (p-value, 95% CI)] G1/G2: NSS Insulin-dependent diabetes, n (%): G1: 0 G2: 2 (5.4 %) [test, result (p-value, 95% CI)] G1/G2:

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
	<p>G2: 37 G1 4 decreased or transferred early, 4 complicated infection G2 2 deceased of transferred, 1 complicated</p> <p>Average follow-up, days: [mean (SD), median (range/IQR)] G1: G2: Follow-up 28 days</p>	<p>Sepsis, ATS, RCCM, 1992 Condition = definition: Septic shock, ATS, RCCM, 1992</p>		<p>Other sepsis, n, (%): G1: 2 (6.5 %) G2: 1 (2.7 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Septic shock, n, (%): G1: 15 (48.4 %) G2: 16 (43.2 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>SAPS III, mean (SD): G1: 68.5 (12.1) G2: 70.1 (13.1) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>SOFA, Mean (SD): G1: 6.4 (3.3) G2: 6.6 (3.0) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Baseline PCT, Median (range): G1: 7.3 (0.1-93) G2: 5.4 (0.1-354) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Baseline PCT < 1.0, n, (%): G1: 7 (22.5 %) G2: 6 (16.2) [test, result (p-value, 95% CI)]</p>	<p>Non-insulin-dependent diabetes, n (%): G1: 4 (12.9 %) G2: 6 (16.2 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Chronic renal failure, n (%): G1: 2 (6.5 %) G2: 6 (16.2 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Peripheral vascular disease, n (%): G1: 1 (3.2 %) G2: 1 (2.72 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Chronic liver disease, n (%): G1: 5 (16.1 %) G2: 5 (13.5 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p>

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
				CI]) G1/G2: NSS	

Evidence Table 2 L. Intermediate Outcomes for Nobre et al., 2008.¹²

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
Intent to treat Duration antibiotics, Days: Median (range) G1: 6 (3-24) G2: 9.5 (2-33) [test, result (p-value, 95% CI)] G1/G2: Mean difference 2.6 (-0.3 to 5.5), p = 0.15 Incidence density antibiotic exposure: (rate days exposed per 1,000 patient-days) G1: 541 G2: 644 [test, result (p-value, 95% CI)] G1/G2: Mean difference 1.1 (0.9 to 1.3), p = 0.07 Days alive without antibiotics, mean (SD): G1: 15.3 (8.9) G2: 13 (8.2) [test, result (p-value, 95% CI)] G1/G2: Mean difference 2.3 (-5.9 to 1.8), p = 0.28 Per protocol Duration antibiotics, Days: Median (range) G1: 6 (4-16) G2: 10 (3-33) [test, result (p-value, 95% CI)] G1/G2: Mean difference 3.2	NR	NR	Intent to treat Days: [mean (SD), median (range) G1: 17 (3-96) G2: 23.5 (5-44) [test, result (p-value, 95% CI)] G1/G2: NSS Per protocol Days: [mean (SD), median (range) G1: 14 (5-64) G2: 21 (5-89) [test, result (p-value, 95% CI)] G1/G2: NSS	Intent to treat ICU LOS, Days: [mean (SD), median (range) G1: 4 (1-21) G2: 7 (1-91) [test, result (p-value, 95% CI)] G1/G2: p = 0.02 Mean difference 4.6 (1.0 to 8.2) Per protocol ICU LOS, Days: [mean (SD), median (range) G1: 3 (1-8) G2: 5 (1-30) [test, result (p-value, 95% CI)] G1/G2: p = 0.03 Mean difference 4.3 (0.4 to 8.3)

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
(1.1 to 5.4), p = 0.003 Incidence density antibiotic exposure: (rate days exposed per 1,000 patient-days) G1: 504 G2: 655 [<i>test, result (p-value, 95% CI)</i>] G1/G2: Mean difference 1.3 (1.1 to 1.5), p = 0.0002 Days alive without antibiotics, mean (SD): G1: 17.4 (7.6) G2: 13.6 (7.6) [<i>test, result (p-value, 95% CI)</i>] G1/G2: Mean difference 3.8 (0.1 to 7.5), p = 0.04				

Evidence Table 3L: Morbidity Outcomes for Nobre et al., 2008.¹²

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
NR	NR	Intent to treat Relapse infection rate, n (%): G1: 1 (2.6 %) G2: 1 (2.5 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS Per protocol Relapse infection rate, n (%): G1: 1 (3.2 %) G2: 1 (2.7 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS	NR	Intent to treat Clinical cure (%): G1: 31 (79.4 %) G2: 32 (80 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS Per protocol Clinical cure (%): G1: 28 (90.3 %) G2: 31 (83.8 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS

Evidence Table 4L. Mortality Outcomes for Nobre et al., 2008.¹²

In-hospital mortality	28-day mortality	Death	Sepsis--related death	Proportion surviving hospitalization
Intent to treat Proportion (%): G1: 9 (23.1 %) G2: 9 (22.5 %) [test, result (p-value, 95% CI)] G1/G2: NSS	Intent to treat Proportion (%): G1: 8 (20.5 %) G2: 8 (20 %) [test, result (p-value, 95% CI)] G1/G2: NSS	NR	Intent to treat Proportion (%): G1: 3 (37.5 %) G2: 2 (25 %) [test, result (p-value, 95% CI)] G1/G2: NSS	NR
Per protocol Proportion (%): G1: 6 (19.4 %) G2: 7 (18.9 %) [test, result (p-value, 95% CI)] G1/G2: NSS	Per protocol Proportion (%): G1: 5 (16.1 %) G2: 6 (16.2 %) [test, result (p-value, 95% CI)] G1/G2: NSS		Per protocol Proportion (%): G1: 3/5 (60 %) G2: 1/6 (16.6 %) [test, result (p-value, 95% CI)] G1/G2: NSS	

Evidence Table 5L. Function and Quality of Life Outcomes for Nobre et al., 2008.¹²

Days ≤ 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score
NR	NR	NR	NR

Evidence Table 6L: Adverse Effects and Adherence for Nobre et al., 2008.¹²

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence
NR	NR	NR	NR

Evidence Table 7L. Randomized Trial Study Quality Ratings for Nobre et al., 2008.¹²

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results
Y	Y	Y	Y	Y	Y	Y

Evidence Table 1M. Study Description Table for Schuetz et al., 2009.¹³

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Schuetz et al., 2009. (ProHOSP)	Design: RCT, 1:1, non-inferiority	Primary outcome: Overall adverse event rate within 30 days (death, ICU, disease-specific complications, recurrence), non-inferiority Both intent to treat and per protocol analysis performed for primary outcomes	Inclusion criteria: <ul style="list-style-type: none"> ED patients with LRTIs Age > 18 years Duration of illness < 28 days 1 respiratory symptom, 1 physical finding OR fever OR leukocytosis Exclusion criteria: <ul style="list-style-type: none"> Intravenous drug use Severe immunosuppression (except corticosteroids) HAP Chronic infection Imminent death 	Age, years: [mean (SD), median (range/IQR)] G1: 73 (59-82) G2: 72 (59-82) [test, result (p-value, 95% CI)] G1/G2: NSS	Coronary artery disease, n (%): [test, result (p-value, 95% CI)] G1: 146 (21.8 %) G2: 136 (19.8 %) G1/G2:

Country, institution type:
 Switzerland, multi-center, tertiary care hospitals (6 hospitals)

Enrollment period:
 October 2006-March 2008

Funding:
 Swiss Nat'l Science Foundation; Gottry and Julia Bangerter-Rhyner Foundation, the University Hospital of Basel; the Medical University Clinic Liestal; the Medical Clinic Buergerhospital Solothurn; the Cantonal Hospitals Muensterlingen; the Swiss Society for Internal Medicine; Brahms supplied the diagnostic kits

Author industry relationship disclosures:
 3 authors with support from Brahms; 1 author consultant for Brahms

Interventions:
G1: PCT-guided initiation of antibiotics; PCT-guided discontinuation of antibiotics
G2: Standard therapy

Presenting condition:
 LRTI; CAP, AECOPD, acute bronchitis, other

Setting:
 EDs

1825 with LRTI in Eds
 1359 randomized

N at enrollment:
G1: 687
G2: 694

N at follow-up:
G1: 671
G2: 688

G1: 34 died, 16 withdrew, 1 LTFU
G2: 33 died, 6 withdrew, 0 LTFU

Average follow-up, days: [mean (SD), median (range/IQR)]

Study powered to detect a 7.5 % increase in combined endpoint; 90 % chance of detection, needed 1002 patients

Secondary outcome:
 Antibiotic exposure
 Duration of antibiotics
 Adverse antibiotic effects
 LOS

Superiority

Response criteria, independent outcome assessor:
 Outcomes assessed by blinded investigators

Assay type:
 Rapid Kryptor, Brahms

Decision-making:
G1:
G2:

Male, n (%):
G1: 402 (59.9 %)
G2: 380 (55.2 %)
 [test, result (p-value, 95% CI)]

G1/G2: NSS

Disease
CAP, n, (%): [mean (SD), median (range/IQR)]
G1: 460 (68.6 %)
G2: 465 (67.6 %)
 [test, result (p-value, 95% CI)]

G1/G2:

PSI for CAP, n, (%):
 [mean (SD), median (range/IQR)]
G1: 91 (67-117)
G2: 91 (66-114)
 [test, result (p-value, 95% CI)]

G1/G2: NSS

Over 50 % of patients with CAP were high-risk by PSI

AECOPD, n, (%): [mean

Coronary artery disease, n (%):
 [test, result (p-value, 95% CI)]
G1: 146 (21.8 %)
G2: 136 (19.8 %)
G1/G2:

Cerebrovascular disease, n (%):
 [test, result (p-value, 95% CI)]
G1: 54 (8.1 %)
G2: 56 (8.1 %)
G1/G2:

Renal dysfunction, n (%):
 [test, result (p-value, 95% CI)]
G1: 156 (23.3 %)
G2: 146 (21.2 %)
G1/G2:

COPD, n, (%):
 [test, result (p-value, 95% CI)]
G1: 265 (39.5 %)
G2: 268 (39.0 %)
G1/G2:

Cancer, n (%):
 [test, result (p-value, 95% CI)]
G1: 69 (10.3 %)
G2: 98 (14.2 %)
G1/G2:

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
	<p>G1: G2: Duration of follow-up 30 days (phone interview)</p>	<p>Algorithm for PCT guided therapy For antibiotic initiation PCT < 0.1, antibiotics strongly discouraged; PCT \leq 0.25, antibiotics discouraged; PCT > 0.25, antibiotics encouraged; PCT > 0.5, antibiotics strongly encouraged</p> <p>For antibiotic discontinuation PCT < 10 % of baseline, stopping antibiotics strongly encouraged; PCT < 20 % of baseline, stopping antibiotics discouraged</p> <p>Protocol could be overruled if ICU, hemodynamic instability, + Legionella Other interventions adequate antibiotic therapy</p> <p>Condition = definition: CAP = new infiltrate</p> <p>Condition = definition: COPD = GOLD criteria</p>		<p>(SD), median (range/IQR)] G1: 115 (17.1 %) G2: 113 (16.4 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Acute bronchitis, n, (%): [mean (SD), median (range/IQR)] G1: 69 (10.3 %) G2: 82 (11.9 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Other, n, (%): [mean (SD), median (range/IQR)] G1: 27 (4.0 %) G2: 28 (4.0 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Hospitalized, n, (%): [mean (SD), median (range/IQR)] G1: 628 (93.7 %) G2: 629 (91.4 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p>	<p>Diabetes mellitus, n (%): G1: 118 (17.0 %) G2: 113 (16.4 %) [test, result (p-value, 95% CI)] G1/G2:</p>

Evidence Table 2 M. Intermediate Outcomes for Schuetz et al., 2009.¹³

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
<p>Days: Mean, (median/ IQR)] G1: 5.7 (5/1-8) G2: 8.7 (9/6-11)</p> <p>[test, result (p-value, 95% CI)] G1/G2: % difference 95% CI, -34.8 (-40.3 to -28.7)</p>	<p>Any antibiotic use, antibiotic prescription rate, n, (%): G1: 506/671 (75.4 %) G2: 603/688 (87.7 %)</p> <p>[test, result (p-value, 95% CI)] G1/G2: CI -12.2 (-16.3 to -8.1)</p>	NR	<p>Days: Mean, (median/IQR) G1: 9.4 (8/4-12) G2: 9.2 (8/4-12)</p> <p>[test, result (p-value, 95% CI)] G1/G2: Relative mean change 1.8 (-6.9 to 11.0)</p>	NR

Evidence Table 3M. Morbidity Outcomes for Schuetz et al., 2009.¹³

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
<p>Intent to Treat</p> <p>Overall adverse outcome, n, (%): G1: 103/671 (15.4 %) G2: 130/688 (18.9 %)</p> <p>[test, result (p-value, 95% CI)] G1/G2: CI for difference by Mantel-Haenszel weights stratified by site of infection. -3.5 (-7.6 to 0.4)</p> <p>Kaplan-Meier curves for time to first adverse event were calculated</p> <p>ICU, n, (%): G1: 43/671 (6.4 %) G2: 60/688 (8.7 %)</p> <p>[test, result (p-value, 95% CI)] G1/G2: CI -2.3 (-5.2 to 0.4)</p> <p>Disease-specific complications (%): G1: 17/671 (2.5 %) G2: 14/688 (2.0 %)</p> <p>[test, result (p-value, 95% CI)] G1/G2:</p> <p>Per protocol</p> <p>Overall adverse outcome, n, (%): G1: 95/633 (15.0 %) G2: 123/650 (18.9 %)</p> <p>[test, result (p-value, 95% CI)] G1/G2: -3.9 (-8.2 to 0.03)</p>	<p>Antibiotic adverse effects, n, (%): [mean (SD), median (range/IQR)] G1: 133/671 (19.8 %) G2: 193/688 (28.1 %)</p> <p>[test, result (p-value, 95% CI)] G1/G2: CI -8.2 (-12.7 to -3.7)</p>	<p>Intent to Treat</p> <p>Recurrence of infection (%): G1: 25/671 (3.7 %) G2: 45/688 (6.5 %)</p> <p>[test, result (p-value, 95% CI)] G1/G2: CI -2.8 (-5.1 to -0.4)</p>	NR	NR

Evidence Table 4M. Mortality Outcomes for Schuetz et al., 2009.¹³

In-hospital mortality	30-day mortality	Death	Pneumonia-related death	Proportion surviving hospitalization
NR	Intent to treat Proportion, n, (%): G1: 34/671 (5.1 %) G2: 33/688 (4.8 %) [test, result (p-value, 95% CI)] G1/G2: CI 0.3 (-2.1 to 2.5) Per protocol Proportion, n, (%): G1: 29/633 (4.6 %) G2: 31/650 (4.8 %) [test, result (p-value, 95% CI)] G1/G2:	NR	NR	NR

Evidence Table 5M. Function and Quality of Life Outcomes for Schuetz et al., 2009.¹³

Days ≤ 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score
NR	NR	NR	NR

Evidence Table 6M. Adverse Effects and Adherence for Schuetz et al., 2009.¹³

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence
NR	NR	NR	NR

Evidence Table 7M. Randomized Trial Study Quality Ratings for Schuetz et al., 2009.¹³

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results
Y-balanced Y-concealment	Y	Y	Y	Y	Y	Y

Evidence Table 1N. Study Description Table for Schroeder et al., 2009.¹⁴

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Schroeder et al., 2009. Country, institution type: Germany, University hospital SICU Enrollment period: October 2006-April 2007 Funding: None listed Author industry relationship disclosures: 1 author Brahms speaker's bureau, no other conflicts	Design: RCT, 1:1 Interventions: G1: PCT-guided antibiotic therapy G2: Standard therapy Presenting condition: Status-post abdominal surgery Setting: SICU 125 screened 27 met inclusion criteria N at enrollment: G1: 14 G2: 13 N at follow-up: G1: 14 G2: 13 Average follow-up, days: [mean (SD), median (range/IQR)] G1: G2:	Primary outcome: Response criteria, independent outcome assessor: No power calculation Assay type: Kryptor, Brahms Also CRP, IL-6, WBC Decision-making: G1: PCT decreased to 1 or 25-35 % of baseline over 3 days G2: Standard Condition = definition: Severe sepsis, 1992 ATS, RCCM	Inclusion criteria: <ul style="list-style-type: none"> • Status-post abdominal surgery • Severe sepsis Inclusion criteria: <ul style="list-style-type: none"> • None listed 	Age, years: [mean (SD), median (range/IQR)] G1: 69.3 (10.6) G2: 68.4 (13.7) Male, n (%): G1: 8/14 G2: 7/13 Disease Pneumonia, n, (%): [mean (SD), median (range/IQR)] G1: 4/14 G2: 4/13 Disease Peritonitis, n, (%): [mean (SD), median (range/IQR)] G1: 10/14 G2: 9/13 SAPS II, Mean (SD): [test, result (p-value, 95% CI)] G1: 45.6± 18.5 G2: 53.7 ±14.7 G1/G2: NSS SOFA max, Mean (SD): G1: 7.3 (3.5) G2: 8.3 (4.2) [test, result (p-value, 95% CI)] G1/G2: NSS	

Evidence Table 2 N. Intermediate Outcomes for Schroeder et al., 2009.¹⁴

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
Days: [mean (SD), median (range/IQR)] G1: 6.6 (1.1) G2: 8.3 (0.7) [test, result (p-value, 95% CI)] G1/G2: p < 0.001	NR	NR	NR	ICU admission, days: [mean (SD), median (range/IQR)] G1: 16.4 (8.3) G2: 16.7 (5.6) [test, result (p-value, 95% CI)] G1/G2: NSS

Evidence Table 3N. Morbidity Outcomes for Schroeder et al., 2009.¹⁴

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
NR	NR	NR	NR	NR

Evidence Table 4N. Mortality Outcomes for Schroeder et al., 2009.¹⁴

In-hospital mortality	28-day mortality	Death	Pneumonia-related death	Proportion surviving hospitalization
NR	NR	Proportion (%): G1: 3/14 G2: 3/13 [test, result (p-value, 95% CI)] G1/G2: NSS	NR	NR

Evidence Table 5N. Function and Quality of Life Outcomes for Schroeder et al., 2009.¹⁴

Days ≤ 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score
NR	NR	NR	NR

Evidence Table 6N. Adverse Effects and Adherence¹⁴

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence
NR	NR	NR	NR

Evidence Table 7N. Randomized Trial Study Quality Ratings for Schroeder et al., 2009.¹⁴

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results
Y*	Y	Y	Y	Y	Y	Y

*No details on allocation concealment but groups were comparable

Evidence Table 10. Study Description Table for Stocker et al., 2010.¹⁵

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Stocker et al., 2010. Country, institution type: Switzerland, single tertiary care institution Enrollment period: June 1, 2005-December 31, 2006 Funding: Brahms supplied test kits Author industry relationship disclosures: Not given	Design: RCT; 1:1, masked until randomization Interventions: G1: G2: Presenting condition: Suspected early-onset neonatal sepsis Setting: Neonatal and Pediatric ICU 126 screened, 5 excluded (2 no consent, 2 protocol errors, and 1 surgery in first 3 days) N at enrollment: G1: 60 G2: 61 N at follow-up: G1: 60 G2: 61 Average follow-up, days: [mean (SD), median (range/IQR)] G1: 3 days to 1 month G2: 3 days to 1 month	Primary outcome: Proportion of infants treated with antibiotics \geq 72 hours Absolute reduction in duration of antibiotic therapy Trial 90 % powered to detect a 30 % difference in duration of antibiotic therapy Secondary outcome: Survival Recurrence of infection in first month (antibiotics given $>$ 120 hours) Assay type: Kryptor, Brahms Decision-making: G1: PCT age-adjusted for 0-120 hours of age, peak at 18-30 hours of 10 ng/mL G2: Standard therapy Condition = definition: Sepsis Diagnosis by risk factors, group B streptococcus, premature rupture of membranes, clinical status, including respiratory distress, tachycardia, bradycardia, hypotension, seizures, irritability, vomiting, feeding intolerance, ileus, WBC	Inclusion criteria: <ul style="list-style-type: none"> Gestational age \geq 34 weeks Early-onset sepsis (3 days) Exclusion criteria: <ul style="list-style-type: none"> Severe congenital malformations, , Chromosomal abnormalities Surgery in first 3 days of life 	Gestational age (weeks), mean (std dev): [test, result (p-value, 95% CI)] G1: 39.4 (34.4-42.0) G2: 39.7 (34.0-41.7) G1/G2: NSS APGAR 5, mean (std dev): G1: 9 G2: 9 [test, result (p-value, 95% CI)] APGAR 10, mean (std dev): G1: 9 G2: 10 [test, result (p-value, 95% CI)] G1/G2: NSS Infection proven/probable, n, (%): G1: 9/0 (15 %) G2: 11/1 (20 %) [test, result (p-value, 95% CI)] G1/G2: NSS Male sex, n, (%): G1: 35 (58 %) G2: 40 (65 %) [test, result (p-value, 95% CI)] G1/G2: NSS Normal spontaneous vaginal delivery, n (%): G1: 36 (60 %) G2: 31 (51 %) [test, result (p-value, 95% CI)] G1/G2: NSS Infection possible, n, (%): G1: 21 (35 %) G2: 19/1(31 %) [test, result (p-value, 95% CI)] G1/G2: NSS Infection unlikely, n, (%): G1: 30 (50 %) G2: 30.1 (49 %) [test, result (p-value, 95% CI)]	

		count, immature to total granulocytes, CRP		G1/G2: NSS	G1/G2: NSS
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Evidence Table 2 O. Intermediate Outcomes for Stocker et al., 2010.¹⁵

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
<p>Reduction in duration of antibiotics (hours), mean (std dev):</p> <p>All newborns G1: 79.1 G2: 101.5 [test, result (p-value, 95% CI)] G1/G2: Abs reduction 22.4, Mann-Whitney U test, p = 0.012</p> <p>Infection proven/probably G1: 177.8 G2: 170.8 [test, result (p-value, 95% CI)] G1/G2: Abs reduction 7, NSS</p> <p>Infection possible G1: 83.4 G2: 111.5 [test, result (p-value, 95% CI)] G1/G2: Abs reduction 28.1, p < 0.001</p> <p>Infection unlikely G1: 46.5 G2: 67.4 [test, result (p-value, 95% CI)] G1/G2: Abs reduction 20.9, p = 0.001</p>	<p>Proportion treated with antibiotics > 72 hours, n, %: [mean (SD), median (range/IQR)]</p> <p>All newborns G1: 33/60 (55 %) G2: 50/61 (82 %) [test, result (p-value, 95% CI)] G1/G2: RR 27 %, Fisher's exact test, p = 0.002</p> <p>Infection proven/probably G1: 9/9 (100 %) G2: 12/12 (100 %) [test, result (p-value, 95% CI)] G1/G2: RR 0 %, NSS</p> <p>Infection possible G1: 13/21 (61.9 %) G2: 19/19 (100 %) [test, result (p-value, 95% CI)] G1/G2: RR 38.1 %, p < 0.001</p> <p>Infection unlikely G1: 11/30 (36.7 %) G2: 19/30 (63.3 %) [test, result (p-value, 95% CI)] G1/G2: RR, 26.6 %, p = 0.038</p>	NR	NR	NR

Evidence Table 3O. Morbidity Outcomes for Stocker et al., 2010.¹⁵

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
NR	NR	Recurrence (%): G1: 32 % G2: 39 % [test, result (p-value, 95% CI)] G1/G2: OR 0.71, 95 % CI 0.34/1.51, Fisher's exact test, non-inferiority, NSS	NR	NR

Evidence Table 4O. Mortality Outcomes for Stocker et al., 2010.¹⁵

In-hospital mortality	28-day mortality	Death	Pneumonia-related death	Proportion surviving hospitalization
Proportion (%): G1: 0 % G2: 0 % [test, result (p-value, 95% CI)] G1/G2: NSS	NR	NR	NR	NR

Evidence Table 5O. Function and Quality of Life Outcomes for Stocker et al., 2010.¹⁵

Days < 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score
NR	NR	NR	NR

Evidence Table 6O. Adverse Effects and Adherence for Stocker et al., 2010.¹⁵

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence
NR	NR	NR	NR

Evidence Table 7O. Randomized Trial Study Quality Ratings for Stocker et al., 2010.¹⁵

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results
Y	Y	Y	Y	Y	Y	Y

Evidence Table 1P. Study Description Table for Stolz et al., 2007.¹⁶

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Stolz et al., 2007. Country, institution type: Switzerland, University Hospital of Basel Enrollment period: November 2003-March 2005 Funding: Clinic of Pulmonary Medicine; Clinic of Endo, Diabetes, and Clinical Nutrition; ED of University Hospital of Basel; Brahms supplied the kits Author industry relationship disclosures: I author a consultant and recipient of payments for meetings, travel, speaking, and research; no other conflicts reported	Design: RCT; 1:1, masked until randomization, single center Interventions: G1: G2: Presenting condition: AECOPD Setting: ED N at enrollment: G1: 102 G2: 106 N at 14 days follow-up: blinded G1: 99 (3 deaths) G2: 104 (2 deaths) N at 6 months follow-up: blinded G1: 97 (2 deaths) G2: 97 (7 deaths)	Primary outcome: Antibiotic use at index ECOPD Antibiotic use up to 6 months Secondary outcomes: Success, LOS, ICU need, CRP, PCT, PFTs on admission, short- and long-term follow-up, exacerbation rate, time to next exacerbation Time to clinic events by Kaplan-Meier and log-rank test 85 % chance of detecting a 30 % reduction in antibiotic use, alpha error of 0.05; needed 223 patients enrolled assuming a 20 % dropout rate Response criteria, independent outcome assessor: Assay type: Kryptor PCT, Brahms Decision-making: G1: For antibiotic	Inclusion criteria: <ul style="list-style-type: none"> • ≥ 40 years of age • Met post-bronchodilator therapy criteria for E-COPD within 48 hours of ED admission Exclusion criteria: <ul style="list-style-type: none"> • Other explanation for illness • Psychiatric comorbidities • Immunosuppression • Asthma • Cystic fibrosis • Infiltrate on CXR 	Age, years: median (range/IQR) G1: 69.5 (65-77) G2: 69.5 (64.8-79) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS Men, n (%): G1: 50 (49 %) G2: 44 (41.5 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS Current smoker, n (%): G1: 40 (39.2 %) G2: 54 (50.9 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS Pack-years: median (range/IQR) G1: 43 (30-58.5) G2: 50 (30-60) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS HTN, n (%): G1: 23 (22.5 %) G2: 27 (25.5 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS COPD duration, months: [mean (SD)] G1: 128 (82) G2: 123 (85) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS	Diabetes mellitus, n (%): G1: 12 (11.8) G2: 11 (10.4) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS Renal insufficiency, n (%): G1: 5 (4.9 %) G2: 12 (11.3 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS Cardiomyopathy, n (%): G1: 42 (41.2) G2: 49 (46.2) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS Osteoporosis, n (%): G1: 17 (16.7 %) G2: 9 (8.5 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
		<p>initiation PCT < 0.1 antibiotics strongly discouraged;</p> <p>PCT $\geq 1.0 \leq 0.25$, antibiotics based on clinical condition;</p> <p>PCT > 0.25, antibiotics encouraged</p> <p>G2: Standard management</p>		<p>G1/G2: NSS</p> <p>AECOPD previous year: [mean (SD): G1: 2.4 (2.1) G2: 1.9 (1.8) [<i>test, result (p-value, 95% CI)</i>]]</p> <p>G1/G2: NSS</p> <p>Severity of COPD (GOLD staging), n, (%): G1- I: 6 (5.9 %) G1- II: 15 (14.7 %) G1- III: 47 (46.1 %) G1- IV: 34 (33.3 %) G2- I: 5 (4.7 %) G2- II: 25 (23.6 %) G2- III: 51 (48.1 %) G2- IV: 25 (23.6 %) [<i>test, result (p-value, 95% CI)</i>]]</p> <p>G1/G2: NSS</p> <p>Home oxygen, n, (%): G1: 21 (20.6 %) G2: 13 (12.3 %) [<i>test, result (p-value, 95% CI)</i>]]</p> <p>G1/G2: NSS</p> <p>Severity of AECOPD, n, (%): G1- 1: 51 (50 %) G1- 2: 24 (23.5 %) G1- 3: 27 (26.5 %) G2- 1: 49 (46.2 %) G2- 2: 28 (26.4 %) G2- 3: 29 (27.4 %) [<i>test, result (p-value, 95% CI)</i>]]</p>	<p>Cancer, n (%): G1: 12 (11.8 %) G2: 14 (13.2 %) [<i>test, result (p-value, 95% CI)</i>]]</p> <p>G1/G2: NSS</p>

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
				<p>G1/G2: NSS</p> <p>FEV1: [mean (SD): G1: 0.88 (0.41) G2: 0.98 (0.41) [test, result (p-value, 95% CI)]] G1/G2: p = 0.02</p> <p>Positive sputum culture, n, (%): G1: 37 (36 %) G2: 40 (38 %) [test, result (p-value, 95% CI)]] G1/G2: NSS</p> <p>Mostly gram negative rods and Pneumococcus</p> <p>PCT: mean,(SD): G1: 0.274 (1.049) G2: 0.244 (0.516) [test, result (p-value, 95% CI)]] G1/G2: NSS</p> <p>CRP, mean,(SD): G1: 32 (42) G2: 44 (55) [test, result (p-value, 95% CI)]] G1/G2: NSS</p> <p>WBC count: mean,(SD): G1: 11.7 (8.4) G2: 11.5 (4.6) [test, result (p-value, 95% CI)]] G1/G2: NSS</p>	

Evidence Table 2 P. Intermediate Outcomes for Stoltz et al., 2007.¹⁶

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
<p>Antibiotic exposure: (rate days exposed per #patient-days)</p> <p>G1: [test, result (p-value, 95% CI)]</p> <p>G2: [test, result (p-value, 95% CI)]</p> <p>G1/G2:</p> <p>Absolute risk reduction 31.5 (18.7 to 44.3), p < 0.0001</p> <p>RR 0.56 (0.43 to 0.73), p<0.0001</p> <p>RRR 44% (27 to 57%), p < 0.0001</p> <p>At 6 months RR 0.76, (0.64 to 0.92), p = 0.004</p> <p>Subsequent antibiotic use within 6 months (%):</p> <p>G1: 46</p> <p>G2: 43</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>Steroid use, n, (%):</p> <p>G1: 89 (87.3 %)</p> <p>G2: 93 (87.7 %)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>Steroid dose, median, range:</p> <p>G1: 250 (119-400)</p> <p>G2: 280 (183-421)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p>	<p>Any antibiotic use, antibiotic prescription rate (%):</p> <p>G1: 40 %</p> <p>G2: 72 %</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: p < 0.0001</p> <p>Number of courses of antibiotics: [mean (SD), median (range/IQR)]</p> <p>G1:</p> <p>G2:</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2:</p>	<p>Antibiotic classes, n (%):</p> <p>G1-1 antibiotic: 80 %</p> <p>G1-2 antibiotic: 15 %</p> <p>G1-3 antibiotic: 2 %</p> <p>G2-1 antibiotic: 68 %</p> <p>G2-2 antibiotic: 29 %</p> <p>G2-3 antibiotic: 3 %</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>Antibiotics prescribed were amino penicillin's (62 %), fluoroquinolones (16 %), cephalosporin's (11 %), macrolides (8 %), anti-Pseudomonas aeruginosa penicillin's (2 %), and other (1 %)</p>	<p>Days: [mean (SD), median (range/IQR)]</p> <p>G1: 9 (1-15)</p> <p>G2: 10 (1-15)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>Hospital LOS < 24 hours, n, (%):</p> <p>G1: 22 (21.6 %)</p> <p>G2: 24 (22.6 %)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p>	<p>ICU admission (%):</p> <p>G1: 8 (7.8 %)</p> <p>G2: 11 (10.4 %)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>ICU LOS, days: mean (SD)</p> <p>G1: 3.3 (2.7)</p> <p>G2: 3.7 (2.1)</p> <p>[test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p>

Evidence Table 3P. Morbidity Outcomes for Stolz et al., 2007.¹⁶

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
NR	<p>FEV1 at 14 days, mean (SD): G1: 1.04 (0.48) G2: 1.01 (0.57)</p> <p>G1/G2: NSS</p> <p>FEV1 at 6 months, mean (SD): G1: 1.07 (0.55) G2: 1.11 (0.57)</p> <p>G1/G2: NSS</p>	<p>Recurrence of AECOPD 6 months, n, (%): G1: 44 (43.1 %) G2: 43 (40.1 %) [test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p> <p>Hospitalization for recurrence of AECOPD 6 months, n, (%): G1: 18 (17.7 %) G2: 22 (20.8 %) [test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p>	NR	<p>Clinical cure (%): G1: 84 (82.4 %) G2: 89 (83.9 %) [test, result (p-value, 95% CI)]</p> <p>G1/G2:</p>

Evidence Table 4P. Mortality Outcomes for Stolz et al., 2007.¹⁶

In-hospital mortality	28-day mortality	Death within 6 months	Pneumonia-related death	Proportion surviving hospitalization
NR	NR	<p>Death of any cause, n (%): G1: 5 (4.9 %) G2: 9 (8.5 %) [test, result (p-value, 95% CI)]</p> <p>G1/G2: NSS</p>	NR	NR

Evidence Table 5P. Function and Quality of Life Outcomes for Stolz et al., 2007.¹⁶

Days < 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score
NR	NR	NR	NR

Evidence Table 6P. Adverse Effects and Adherence for Stolz et al., 2007.¹⁶

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence
NR	NR	NR	NR

Evidence Table 7P. Randomized Trial Study Quality Ratings for Stolz et al., 2007.¹⁶

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results
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Y-balanced U-concealment	Y	Y	Y	Y	Y	N
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Evidence Table 1Q. Study Description Table for Stolz et al., 2009.¹⁷

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Stolz et al., 2009. (ProVAP)	Design: Multi-national, RCT, 1:1, open interventional, 7 ICUs	Primary outcome: Antibiotic-free days alive assessed at 28 days After enrollment Secondary outcomes Vent-free days, ICU-free days, clinical evidence of progression, and mortality	Inclusion criteria: <ul style="list-style-type: none"> In ICU on vent > 48 hours Age > 18 years VAP by ATS criteria Exclusion criteria: <ul style="list-style-type: none"> Pregnant Enrolled in another trial On immuno-suppressants or long-term corticosteroids (> 1 month) Severely immunosuppressed (AIDS, etc.) Extra-pulmonary infections 	Age, years: [mean (SD), median (range/IQR)] G1: 53 (21-88) G2: 59 (18-83) [test, result (p-value, 95% CI)]	Coronary artery disease, n (%): G1: 9 (18 %) G2: 4 (8 %) [test, result (p-value, 95% CI)] G1/G2: NSS

Country, institution type:
 Switzerland, USA

Enrollment period:
 Not given

Funding:
 Swiss Nat'l Foundation; Margarete and Walter Liechtenstein Foundation; Friewillige Akademische Gesellschaft Basel; Will Rogers Foundation; Clinic of Pulmonary Medicine-University Hospital Basel; Brahms, Germany

Author industry relationship disclosures:
 Statement at website

Interventions:

G1:
G2:

Presenting condition:
 VAP

Setting:
 ICU

N at enrollment:

G1: 51
G2: 50

N at follow-up:
G1: 51
G2: 50

Average follow-up, days: [mean (SD), median (range/IQR)]
G1:
G2:

Patients re-evaluated daily up to 10 days after inclusion

164 patients screened
 23 unable to consent
 1 mental retardation
 6 refused consent

Primary outcome:

Antibiotic-free days alive assessed at 28 days

After enrollment
 Secondary outcomes Vent-free days, ICU-free days, clinical evidence of progression, and mortality

Superiority trial for antibiotic free days.

84 patients needed to have a 90 % chance of detecting a 5 day difference

100 enrolled assuming 8 % lost to follow-up

Response criteria, independent outcome assessor:

Assay type:
 Kryptor, Brahms

Decision-making:

Measured at baseline, at 72 hours, and daily up to 10 days

After 72 hours of empiric antibiotics, daily PCT reported to physician

- In ICU on vent > 48 hours
- Age > 18 years
- VAP by ATS criteria

Exclusion criteria:

- Pregnant
- Enrolled in another trial
- On immuno-suppressants or long-term corticosteroids (> 1 month)
- Severely immunosuppressed (AIDS, etc.)
- Extra-pulmonary infections

Age, years: [mean (SD), median (range/IQR)]
G1: 53 (21-88)
G2: 59 (18-83)
 [test, result (p-value, 95% CI)]

G1/G2:

Male, n (%):
G1: 38 (75 %)
G2: 37 (74 %)
 [test, result (p-value, 95% CI)]

G1/G2: NSS

Admission Medical, n (%):
G1: 27 (53 %)
G2: 26 (52 %)
 [test, result (p-value, 95% CI)]

G1/G2: NSS

Congestive heart failure, n (%):
G1: 21 (41 %)
G2: 27 (54 %)
 [test, result (p-value, 95% CI)]

G1/G2: NSS

Emergency surgery, n (%):
G1: 23 (45 %)
G2: 20 (40 %)
 [test, result (p-value, 95% CI)]

G1/G2: NSS

Renal dysfunction, n (%):
 [test, result (p-value, 95% CI)]
G1: 9 (18 %)
G2: 7 (14 %)

G1/G2:
Liver disease, n (%):
 [test, result (p-value, 95% CI)]
G1: 4 (8 %)
G2: 3 (6 %)

G1/G2: NSS

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
	<p>3 physician refused 17 immunocompromised 5 CAP 4 death before inclusion 4 other study</p>	<p>G1: PCT < 0.25, d/c antibiotics strongly encouraged, PCT 0.25-0.5 or decrease by 80 % from day 0, d/c antibiotics encouraged, PCT 0.5 or greater or decrease of less than 80 % from baseline, antibiotics encouraged, PCT > 1, antibiotics strongly encouraged</p> <p>G2: Standard antibiotic therapy based on respiratory secretions</p> <p>Condition = definition: VAP by ATS definition</p>		<p>Duration of MV before VAP, days, mean (range): G1: 6 (3-7) G2: 6 (4-10) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Antibiotics before VAP, n (%): G1: 35 (69 %) G2: 41 (82 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Shock, n (%): G1: 11 (22 %) G2: 12 (24 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Bacteremia, n (%): G1: 14 (28 %) G2: 18 (36 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>SAPS II, mean (SD): G1: 42 (13) G2: 45 (14) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>PCT correlated with severity of disease, SAPSII ($r^2=0.358$, $p <$</p>	<p>Diabetes mellitus, n (%): G1: 10 (20 %) G2: 13 (26 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>COPD, n (%): G1: 8 (16 %) G2: 11 (22 %) [test, result (p-value, 95% CI)] G1/G2: NSS</p> <p>Cancer, n (%): [test, result (p-value, 95% CI)] G1: 3 (6 %) G2: 5 (10 %) G1/G2: NSS</p> <p>Substance abuse, n (%): [test, result (p-value, 95% CI)] G1: 5 (10 %) G2: 8 (16 %) G1/G2: NSS</p>

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
				<p>0.001)</p> <p>ODIN, mean (SD): G1: 1.9 (0.9) G2: 2.3 (1.0) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p> <p>SOFA, mean (SD): G1: 7.3 (3.4) G2: 8.2 (3.4) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p> <p>WBC, mean (SD): G1: 12.0 (6.6) G2: 13.3 (5.9) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p> <p>PCT, mean (SD): G1: 0.66 (0.22-2.69) G2: 0.73 (0.21-2.36) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS</p>	

Evidence Table 2 Q. Intermediate Outcomes for Stoltz et al., 2009.¹⁷

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
Superiority Antibiotic-free days at day 28: [mean (SD), median (range/IQR)] G1: 13 (2-21) G2: 9.5 (1.5-17) [<i>test, result (p-value, 95% CI)</i>] G1/G2: $p = 0.049$ Incidence density antibiotic exposure: (rate days exposed per #patient-days) G1: 1,077 G2: 1,341 [<i>test, result (p-value, 95% CI)</i>] G1/G2: Antibiotic duration: G1: 10 (6-16) G2: 15 (10-23) Antibiotics > 7 days, n, %: G1: 65 % G2: 82 %, $p = 0.044$ Antibiotic discontinuation at day 10, HR: 2.235 (CI 1.077-4.64, $p = 0.031$) Duration of antibiotic longer for PSAR, Acinetobacter, Stenotrophomonas, and Klebsiella	Any antibiotic use,	NR	Days: [mean (SD), median (range/IQR)] G1: 26 (7-21) G2: 26 (17-22.3) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS Did not depend on Micro	ICU free days alive: G1: 10 (0-18) G2: 8.5 (0-18) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS Did not depend on Micro

Evidence Table 3Q. Morbidity Outcomes for Stolz et al., 2009.¹⁷

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
Vent-free days, mean (std dev): G1: 21 (2-24) G2: 19(8.5-22.5) [test, result (p-value, 95% CI)] G1/G2: NSS ICU-free days, mean (std dev): G1: 10 (0-18) G2: 8.5 (0-18) [test, result (p-value, 95% CI)] G1/G2: VAP-related deterioration days 1-28, n, %: G1: 5 (10 %) G2: 7 (14 %) [test, result (p-value, 95% CI)] G1/G2: Discharge home days 1-28, n, (%): G1: 5 (10 %) G2: 3 (6 %) [test, result (p-value, 95% CI)] G1/G2: NSS Discharge elsewhere, n, (%): G1: 35 (69 %) G2: 32 (64 %) [test, result (p-value, 95% CI)] G1/G2: NSS	NR	NR	NR	NR

Evidence Table 4Q. Mortality Outcomes for Stolz et al., 2009.¹⁷

In-hospital mortality	28-day mortality	Death	Pneumonia-related death	Proportion surviving hospitalization
Proportion (%): G1: 20 % G2: 28 % [test, result (p-value, 95% CI)]	NR	All causes days 1-28 (%): G1: 8 (16 %) G2: 12 (24 %) [test, result (p-value, 95% CI)]	NR	NR

G1/G2:		G1/G2: NSS	
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Evidence Table 5Q. Function and Quality of Life Outcomes for Stolz et al., 2009.¹⁷

Days ≤ 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score
NR	NR	NR	NR

Evidence Table 6Q. Adverse Effects and Adherence for Stolz et al., 2009.¹⁷

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence	Acquisition or persistence of pathogens up to day 28
NR	NR	NR	NR	NR

Evidence Table 7Q. Randomized Trial Study Quality Ratings for Stolz et al., 2009.¹⁷

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results
Y	Y	Y	Y	Y	Y	Y

Evidence Table 1R. Study Description Table for Svoboda et al., 2007.¹⁸

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Svoboda et al., 2007. Country, institution type: Czech, Academic medical center Enrollment period: May, 2003-September, 2005 Funding: Grant from IGA MZ CR ND 7676-3 Author industry relationship disclosures: Not given	Design: Single center, RCT Interventions: G1: G2: Presenting condition: Multiple trauma (289 ISS≥ 25)settings, 164 major abdominal surgeries (time > 120 minutes) admitted to ICU with severe sepsis Setting: ICU 453 screened 72 enrolled N at enrollment: G1: 38 G2: 34 N at follow-up: G1: G2: Average follow-up, days: [mean (SD), median (range/IQR)] G1: G2:	Primary outcome: No defined prospectively Response criteria, independent outcome assessor: No power calculation Assay type: PCT-Q, Brahms; good correlation with PCT LUMI Also WBC, CRP, IL-6, TNF, and AT III Decision-making: G1: PCT-guided treatment, PCT > 2, change antibiotics and IV catheters; PCT < 2 get US and/or CT with repeat surgical treatment G2: Standard treatment Condition = definition: Severe sepsis. ATS/RCCM definition, 1992.	Inclusion criteria: <ul style="list-style-type: none"> Age > 18 years Inclusion criteria: <ul style="list-style-type: none"> Chemical trauma Burn trauma Moribund patients DNR 	Age, years: median (range) G1: 43 (19-88) G2: 49 (20-86) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS Male, n (%): G1: 23 (61 %) G2: 23 (68 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS Septic shock, n, (SD): G1: 27 (71 %) G2: 23 (68 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS APACHE II, mean (SD): G1: 15.7 (7.9) G2: 17.3 (9.3) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS PCT > 2, n, (%): G1: 21 (55 %) G2: 16 (47 %) G1/G2: NSS	Multiple trauma, n (%): G1: 27 (71 %) G2: 22 (65 %) G1/G2: NSS Abdominal surgery, n (%): G1: 11 (29 %) G2: 12 (35 %) [<i>test, result (p-value, 95% CI)</i>] G1/G2: NSS

Evidence Table 2 R. Intermediate Outcomes for Svoboda et al., 2007.¹⁸

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
NR	NR	NR	NR	ICU LOS, days, mean (SD): G1: 16.1 (6.9) G2: 19.4 (8.9) [test, result (p-value, 95% CI)] G1/G2: p = 0.09

Evidence Table 3R. Morbidity Outcomes for Svoboda et al., 2007.¹⁸

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
SOFA, mean (DS): G1: 7.9 (2.8) G2: 9.3 (3.3) [test, result (p-value, 95% CI)] G1/G2: p = 0.06	Days on ventilation, mean, (SD): G1: 10.3 (7.8) G2: 13.9 (9.4) [test, result (p-value, 95% CI)] G1/G2: p = 0.08	NR	NR	NR

Evidence Table 4R. Mortality Outcomes for Svoboda et al., 2007.¹⁸

In-hospital mortality	28-day mortality	Death	Pneumonia-related death	Proportion surviving hospitalization
NR	Proportion (%): G1: 10 (26 %) G2: 13 (38 %) [test, result (p-value, 95% CI)] G1/G2: NSS	NR	NR	NR

Evidence Table 5R. Function and Quality of Life Outcomes for Svoboda et al., 2007.¹⁸

Days ≤ 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score
NR	NR	NR	NR

Evidence Table 6R. Adverse Effects and Adherence for Svoboda et al., 2007.¹⁸

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence
NR	NR	NR	NR

Evidence Table 7R. Randomized Trial Study Quality Ratings¹⁸

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results
Y	Y	Y	Y	N	Y	Y

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Appendix D. Ongoing Procalcitonin Studies in ClinicalTrials.gov

	NCT ID	Title	Presenting condition(s)	n	Primary outcome	Secondary outcome	Date [†]
1	NCT00914550 ¹	Use Of Procalcitonin Level For Guidance of The Treatment of Suspected Community Acquired Pneumonia [*]	• Pneumonia • Radiographic Lung Infiltrates	100	• Differences in antibiotic discontinuation as an effect of the caregivers learning Procalcitonin levels for the therapy of new radiographic lung infiltrates	-	1-Jun-10
2	NCT01139489 ²	Safety and Efficacy of Procalcitonin Guided Antibiotic Therapy in Adult Intensive Care Units (ICU's) [*]	• Sepsis • Severe Sepsis • Septic Shock	2246	• 28-day mortality • Consumption of antibiotics (defined daily dosage and duration of antibiotic therapy)	• Length of ICU stay • Acquisition costs of antibiotics • Acquisition costs of procalcitonin	1-Jul-11
3	NCT01379547 ³	Procalcitonin to Shorten Antibiotics Duration in ICU Patients [*]	• Sepsis	1700	• Average antibiotics duration • 28-day mortality	• % of antibiotics use • Length of ICU stay • Recurrence of fever • Re-infection • APACHE-II score or SOFA score • 90-day mortality • 90-day infection related readmission rate	1-Jun-13
4	NCT00854932 ⁴	Neonatal Procalcitonin Intervention Study [*]	• Sepsis	1600	• The absolute reduction of the duration of antibiotic therapy with unchanged outcome	• Duration of hospitalization	1-Jul-12
5	NCT00832039 ⁵	Placebo Controlled Trial of Sodium Selenite and Procalcitonin Guided Antimicrobial Therapy in Severe Sepsis [*]	• Severe Sepsis • Septic Shock	1180	• All cause mortality	• SOFA and SOFA subscores • Frequency and duration of mechanical ventilation • Frequency and duration of vasopressor support • Frequency of adverse events and severe adverse events • Clinical cure and microbiological cure • Duration of antimicrobial therapy • Costs of antimicrobial therapy • Time to change of antibiotic therapy • Days alive without antimicrobial therapy	1-Apr-14

	NCT ID	Title	Presenting condition(s)	n	Primary outcome	Secondary outcome	Date [†]
						<ul style="list-style-type: none"> • Frequency of resistance against antibiotics • ICU length of stay • Hospital length of stay • Rate of surgical procedures for focus control • Rate of procedures to diagnose infections • Frequency of new infections 	
6	NCT01018199 ^b	Procalcitonin Versus C-reactive Protein to Guide Therapy in Community Acquired Pneumonia [*]	• Community-Acquired Pneumonia	66	<ul style="list-style-type: none"> • Duration of antibiotic therapy • Total antibiotic exposure days per 1,000 days • Days alive without antibiotics 	<ul style="list-style-type: none"> • All cause 28-day mortality • clinical cure rate • Infection relapse • Length of hospitalization stay • In-hospital mortality • Nosocomial infection rate • Nosocomial superinfection • Isolation of resistant bacteria • All cause 90-day mortality • Costs of hospitalization 	1-Dec-10
7	NCT00987818 ⁷	Procalcitonin Guided Versus Conventional Antibiotic Therapy in Patients With Sepsis in the ICU ^{**}	<ul style="list-style-type: none"> • Sepsis • Intensive Care 	50	<ul style="list-style-type: none"> • Duration of antibiotic therapy 	<ul style="list-style-type: none"> • 28 day mortality 	1-Apr-10
8	NCT01250574 ⁸	Neutrophil CD64 and Procalcitonin as Novel Biomarkers for Postoperative Infections [*]	<ul style="list-style-type: none"> • Bacterial Infection • Postoperative Infection • Abdominal Infection 	150	-	-	-
9	NCT00870623 ⁹	Procalcitonin and Endotoxin Sequential Levels to Optimize the Treatment of Bloodstream Infections [*]	• Infection of Bloodstream	136	<ul style="list-style-type: none"> • Length of treatment by observing the normalization of procalcitonin (PCT) and Endotoxin levels, compared with the length of treatment by standard of care. 	<ul style="list-style-type: none"> • Treatment failure • Complications • Survival, cost • Length of stay • Progression to severe sepsis or superinfections 	-
10	NCT00934011 ¹⁰	Use of Inflammatory Biomarkers to Guide Antibiotic Therapy in Patients With Severe Infections [*]	<ul style="list-style-type: none"> • Severe Sepsis • Septic Shock 	124	<ul style="list-style-type: none"> • Duration of antibiotic therapy • Total antibiotic exposure days per 1,000 days • Days alive without antibiotics 	<ul style="list-style-type: none"> • 28-day mortality • Clinical cure rate • Infection relapse • Length of ICU stay • Nosocomial infection rate • In-hospital mortality 	1-Aug-11

	NCT ID	Title	Presenting condition(s)	n	Primary outcome	Secondary outcome	Date [†]
						<ul style="list-style-type: none"> • Sepsis-associated death • Nosocomial superinfection • Isolation of resistant bacteria <p>Length of hospital stay</p>	
11	NCT01264549 ¹¹	Stroke Adverse Outcome is Associated With Nosocomial Infections: PCTus- Guided Antibacterial Therapy in Severe Ischemic Stroke Patients (STRAWINSKI) [*]	• Ischemic Stroke	200	• Modified Rankin scale	<ul style="list-style-type: none"> • % of patients receiving any antibiotic therapy • % of patients receiving any antibiotic therapy for any duration within 90 days • Barthel Index score • Days alive and out of hospital • Time to first event of death, re-hospitalization or recurrent stroke • Proportion of events of post stroke infections • Median number of days with fever ($\geq 37,5^{\circ}\text{C}$) per patient <p>Stroke volume analysis</p>	1-Dec-12
12	NCT01125098 ¹²	Comparison of a Serum PRO-CT Guided Treatment and the Recommended Antibiotic Treatment for COPD [*]	• COPD	200	• Rate of severe ECOPD	<ul style="list-style-type: none"> • Costs • Duration of antibiotic therapy • Hospital re-admissions • Any cause deaths • FEV1 • Duration of hospitalization for severe ECOPD 	1-Dec-11
13	NCT01091493 ¹³	Utility of Antibiotic Treatment in Non-purulent Exacerbations of Chronic Obstructive Pulmonary Disease: a Double Blinded, Randomized, Placebo-controlled Trial of Security and Efficacy [*]	• COPD	224	• Efficacy of treatment WITHOUT antibiotics in non-purulent exacerbations of COPD	<ul style="list-style-type: none"> • Re-hospitalizations at six months. • In-hospital stay (days) • All cause mortality • Procalcitonin levels • Quality of Life (QoL) (Saint George Respiratory Questionnaire) • CRP levels • Cytokines levels (IL-1, IL-6, IL-8, IL-10) • TNF- alpha levels 	1-Mar-13
14	NCT01311765 ¹⁴	Duration of Antibiotic Therapy in the Treatment of Severe Postoperative Peritonitis	• Postoperative Peritonitis	620	<ul style="list-style-type: none"> • Number of antibiotic-free days at D28 after inclusion • Mortality at D45 after 	<ul style="list-style-type: none"> • Duration of ICU and hospital stay • Changes in SOFA score 	1-Nov-14

	NCT ID	Title	Presenting condition(s)	n	Primary outcome	Secondary outcome	Date [†]
		Peritonitis Admitted in ICU [*]			inclusion	<ul style="list-style-type: none"> • Number of days alive without organ failure • Failure rate for clinically evaluable patients • Failure rate for microbiologically evaluable patients • Rate of relapse within 45 days • Emergence of multidrug resistant microorganisms in clinical isolates and hygiene samples • Total cost of antibiotic agents • Evolution of procalcitonin plasma concentration • Rate of death within 45 days • Total cost of hospital stay and evaluation of costs and resources impact for the hospital administration 	
15	NCT01232140 ^{**}	CRP-guided Antibiotic Treatment in COPD Exacerbations Admitted to the Hospital ^{**}	<ul style="list-style-type: none"> • COPD • ECOPD • Bronchitis 	220	<ul style="list-style-type: none"> • Number of patients treated with antibiotics during hospital stay 	<ul style="list-style-type: none"> • Time to treatment failure within 30-days • Length of stay • Time to next exacerbation • Symptom scores (VAS-LRTI, George's Respiratory Questionnaire) • Adverse events 	1-Jul-13

[†]Expected date of completion of the study, *Study listed as recruiting, ** Study listed as not yet recruiting

1. Use Of Procalcitonin Level For Guidance of The Treatment of Suspected Community Acquired Pneumonia. Available from: <http://clinicaltrials.gov/ct2/show/NCT00914550>. Last accessed 2011 August 18.
2. Safety and Efficacy of Procalcitonin Guided Antibiotic Therapy in Adult Intensive Care Units (ICU's) (SAPS). Available from: <http://clinicaltrials.gov/ct2/show/NCT01139489>. Last accessed 2011 August 18.
3. Procalcitonin to Shorten Antibiotics Duration in ICU Patients (ProShort). Available from: <http://clinicaltrials.gov/ct2/show/NCT01379547>. Last accessed 2011 August 18.
4. Neonatal Procalcitonin Intervention Study (NeoPInS). Available from: <http://clinicaltrials.gov/ct2/show/NCT00854932>. Last accessed 2011 August 18.
5. Placebo Controlled Trial of Sodium Selenite and Procalcitonin Guided Antimicrobial Therapy in Severe Sepsis (SISPCT). Available from: <http://clinicaltrials.gov/ct2/show/NCT00832039>. Last accessed 2011 August 18.
6. Procalcitonin Versus C-reactive Protein to Guide Therapy in Community Acquired Pneumonia (CAP-Marker). Available from: <http://clinicaltrials.gov/ct2/show/NCT01018199>. Last accessed 2011 August 18.
7. Procalcitonin Guided Versus Conventional Antibiotic Therapy in Patients With Sepsis in the ICU. Available from: <http://clinicaltrials.gov/ct2/show/NCT00987818>. Last accessed 2011 August 18.
8. Neutrophil CD64 and Procalcitonin as Novel Biomarkers for Postoperative Infections. Available from: <http://clinicaltrials.gov/ct2/show/NCT01250574>. Last accessed 2011 August 18.
9. Procalcitonin and Endotoxin Sequential Levels to Optimize the Treatment of Bloodstream Infections. Available from: <http://clinicaltrials.gov/ct2/show/NCT00870623>. Last accessed 2011 August 18.
10. Use of Inflammatory Biomarkers to Guide Antibiotic Therapy in Patients With Severe Infections. Available from: <http://clinicaltrials.gov/ct2/show/NCT00934011>. Last accessed 2011 August 18.
11. Stroke Adverse Outcome is Associated With Nosocomial Infections: PCTus- Guided Antibacterial Therapy in Severe Ischemic Stroke Patients (STRAWINSKI). Available from: <http://clinicaltrials.gov/ct2/show/NCT01264549>. Last accessed 2011 August 18.
12. Comparison of a Serum PRO-CT Guided Treatment and the Recommended Antibiotic Treatment for COPD. Available from: <http://clinicaltrials.gov/ct2/show/NCT01125098>. Last accessed 2011 August 18.
13. Utility of Antibiotic Treatment in Non-purulent Exacerbations of Chronic Obstructive Pulmonary Disease: a Double Blinded, Randomized, Placebo-controlled Trial of Security and Efficacy (AEPOC-ATB). Available from: <http://clinicaltrials.gov/ct2/show/NCT01091493>. Last accessed 2011 August 18.
14. Duration of Antibiotic Therapy in the Treatment of Severe Postoperative Peritonitis Admitted in ICU (DURAPOP). Available from: <http://clinicaltrials.gov/ct2/show/NCT01311765>. Last accessed 2011 August 18.
15. CRP-guided Antibiotic Treatment in COPD Exacerbations Admitted to the Hospital (CATCH). Available from: <http://clinicaltrials.gov/ct2/show/NCT01232140>. Last accessed 2011 August 18.

APPENDIX E. Screening Guide for Title and Abstract

Key Questions	Not relevant question Key question1
Study Design	administrative database animal study cost/cost-effectiveness analysis case-control study cohort study commentary case report (n<5) case series design unclear/possibly relevant diagnostic accuracy study editorial guideline in vitro letter meta-analysis no abstract not relevant design no primary data narrative review article phase I trial phase II trial physics study phantom study patient positioning study prognostic study prospective single-arm study quasi-experimental study (nonrandomized comparative) radiology/imaging study randomized controlled trial registry retrospective study systematic review disease staging study cross-sectional study
Study Setting	emergency department hospital wards medical intensive care unit primary care clinic surgical intensive care unit teaching hospital
Age	adult geriatrics neonate pediatrics
Disease	acute bronchitis autoimmune diseases acute lymphoblastic leukemia acute pyelonephritis aspiration syndromes bacteremia bacterial infection community-acquired pneumonia culture-negative sepsis chronic obstructive pulmonary disease chronic bronchitis diabetic foot infection

	empyema fever fungal infection fever of unknown origin hematological tumor H1N1 influenza intra-abdominal infection immunocompromised post-liver transplantation malnutrition meningitis not relevant disease neutropenia neonatal sepsis osteomyelitis peritonitis post-orthopedic surgery post-resuscitation disease parasitic infection sepsis (culture positive) systemic inflammatory response syndrome solid organ tumor septic shock skin/soft tissue infection severe sepsis urinary tract infection ventilator-associated pneumonia viral infection
Biomarker	atrial natriuretic peptide CD14 complement 3 complement 4 C-reactive protein C-terminal pro-atrial vasopressin cell-free plasma DNA interleukin-1b interleukin-4 interleukin-6 interleukin-8 interleukin-10 interleukin-12 lipopolysaccharide binding protein Mid-regional pro-atrial natriuretic peptide macrophage migration inhibitory factor neutrophilic CD64 neopterin procalcitonin (alveolar) procalcitonin (serum) procalcitonin (pleural fluid) soluble triggering receptor expressed on myeloid cells-1 thioredoxin tumor necrosis factor- α TNF receptor II TREM-1
Labs	bronchoalveolar lavage bone biopsy blood cultures erythrocyte sedimentation rate endotracheal aspirate ferritin Gram staining magnetic resonance imaging

	nuclear medicine scan real-time polymerase chain reaction pleural fluid culture swab culture serum sodium urine culture plain radiographs white blood cell count
Outcomes	antibiotic resistance antibiotic-free days antibiotic side effects prediction of bacterial infection detection of complications of infection diagnosis of bacterial infection diagnosis of sepsis duration of intravenous antibiotic total duration of antibiotic therapy initiation of antibiotic therapy length of stay in ICU length of stay in hospital mortality not relevant outcome (or no follow-up) persistent or recurrent fever response to antibiotic therapy septic shock development termination of antibiotic therapy
Assay type	Brahms PCT Kryptor rapid PCT test (semi-quantitative) Vidas Brahms PCT
Sample	n < 10 10 < n < 25 25 < n < 50 50 < n < 100 n > 100 n unclear
Scoring	APACHE II CRB Clinical Pulmonary Infection CURB-65 Sequential Organ Failure Assessment
Retrieval	do not retrieve full copy retrieve full copy uncertain; needs check by second reviewer

APPENDIX F. Screening Guide for Full-text Articles

Population	Does the study include adults or children with suspected local or systemic infection?
Design	Was study designed to compare procalcitonin-guided treatment and comparator-guided treatment (RCT or QEX)?
Outcome	Does the study mention at least one of these outcomes: •changes in patient management •duration of antibiotic therapy •length of stay •antibiotic exposure •morbidity •mortality •function •quality of life •adverse events (associated with testing, persistent/recurrent infection, antibiotic resistance)

APPENDIX G. Data Abstraction Form

Table 1. Study Description

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
Author, year: Country, institution type: Enrollment period: Funding: Author industry relationship disclosures:	Design: Interventions: G1: G2: Presenting condition: Setting: N at enrollment: G1: G2: N at follow-up: G1: G2: Average follow-up, days: [mean (SD), median (range/IQR)] G1: G2:	Primary outcome: Assay type: Decision-making: G1: G2: Condition = definition:	Inclusion criteria: Exclusion criteria:	Age, years: [mean (SD), median (range/IQR)] G1: G2: [test, result (p-value, 95% CI)] G1/G2: Women, n (%): G1: G2: [test, result (p-value, 95% CI)] G1/G2: PCT: [mean (SD), median (range/IQR)] G1: G2: [test, result (p-value, 95% CI)] G1/G2: Infection site, n (%): G1: G2:	CHF (NYHA III/IV), n (%): [test, result (p-value, 95% CI)] G1: G2: G1/G2: Insulin-dependent diabetes, n (%): G1: G2: [test, result (p-value, 95% CI)] G1/G2: Cirrhosis, n (%): G1: G2: [test, result (p-value, 95% CI)] G1/G2: Home oxygen, n (%): G1: G2: [test, result (p-value, 95% CI)] G1/G2: CRF on hemodialysis, n (%): G1: G2: [test, result (p-value, 95% CI)] G1/G2:

Study Description	Study design, interventions, presenting condition, setting, enrollment and follow-up numbers	Primary outcome, procalcitonin assay, decision-making processes, definitions of sepsis and related conditions	Inclusion/exclusion criteria	Participant characteristics	Participant characteristics
					<p>Metastatic cancer, n (%): G1: G2: [<i>test, result (p-value, 95% CI)]</i></p> <p>G1/G2:</p> <p>Immunocompromised, n (%): G1: G2: [<i>test, result (p-value, 95% CI)]</i></p> <p>G1/G2:</p> <p>SAPS II, mean (std dev): G1: G2:</p> <p>SOFA, mean (std dev): G1: G2:</p> <p>Septic shock, n (%): G1: G2:</p>

Table 2. Intermediate Outcomes

Antibiotic treatment duration	Antibiotic prescription rate, number of courses of antibiotics	Antibiotic classes	Hospital length of stay	ICU admission, length of stay
<p>Days without antibiotics at 28 days (superiority): [mean (SD), median (range/IQR)] G1: G2: [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p> <p>Duration of first episode antibiotic treatment, mean (std dev): G1: G2: [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p> <p>Days antibiotic exposure/1,000: (rate days exposed per #patient-days) G1: G2: [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p>			<p>Days: [mean (SD), median (range/IQR)] G1: G2: [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p>	<p>Days: [mean (SD), median (range/IQR)] G1: G2: [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p>

Table 3. Morbidity Outcomes

Morbidity	Morbidity	Recurrence	Sepsis/SIRS frequency	RTI symptoms, overall health, cure, success
<p>SOFA day 28, mean (std dev): G1: G2: [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p>	<p>Mechanical ventilation-free days: [mean (SD), median (range/IQR)] G1: G2: [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p> <p>Nosocomial superinfection, n, (%): G1: G2: [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p> <p>Multi drug resistant, n (%): G1: G2: [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p>	<p>Relapse, n, (%): G1: G2: [<i>test, result (p-value, 95% CI)</i>] G1/G2:</p>		

Table 4. Mortality Outcomes

In-hospital mortality	28-day mortality	60-day mortality	Pneumonia-related death	Proportion surviving hospitalization
	Proportion (%): G1: G2: [test, result (p-value, 95% CI)] G1/G2:	Proportion (%): G1: G2: [test, result (p-value, 95% CI)] G1/G2:		

Table 5. Function and Quality of Life Outcomes

Days ≤ 14 days of baseline with daily activities restricted by RTI	Days work missed	Visual analog functional scale	Quality of life score

Table 6. Adverse Effects and Adherence

Combined adverse outcome < 30 days	Antibiotic adverse effects, days with adverse effects from medication, antibiotic resistance	Pain, bleeding, local infection	Adherence

Table 7. Study Quality Ratings

Assembled comparable groups	Maintained comparable groups	Minimal follow-up loss	Measurements equal, valid, and reliable	Interventions clearly defined	Important outcomes considered	Appropriate analysis of results